

# Exhibit B

Brian Flynn, M.D.

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SUPERIOR COURT OF THE STATE OF CALIFORNIA  
FOR THE COUNTY OF KERN  
CASE NO. 1500-cv-279123 LHB  
Assigned to the Honorable Lorna H. Brumfield  
Reservation No.: 4676

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DEPOSITION OF BRIAN FLYNN, M.D. January 7, 2015

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COLEEN M. PERRY,  
Plaintiff,  
vs.

HUNG T. LUU, M.D.; JOHNSON & JOHNSON, a New Jersey  
corporation; ETHICON, INC., a New Jersey corporation;  
and DOES 1-60,  
Defendants.

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APPEARANCES:

WAGSTAFF & CARTMELL, LLP  
By Jeffrey M. Kuntz, Esq.  
4740 Grand Avenue  
Suite 300  
Kansas City, Missouri 64112  
Appearing telephonically on behalf of  
Plaintiff.

BUTLER SNOW, LLP  
By Nils B. (Burt) Snell, Esq.  
500 Office Center Drive  
Suite 400  
Fort Washington, Pennsylvania 19034  
and

BOWMAN AND BROOKE, LLP  
By Barry J. Koopmann, Esq.  
150 South Fifth Street  
Suite 3000  
Minneapolis, Minnesota 55402  
Appearing on behalf of Defendants.  
Also present: Sean Keith, Esq.

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1 Pursuant to Notice and the California Rules  
 2 of Civil Procedure, the deposition of BRIAN FLYNN, M.D.,  
 3 called by Plaintiff, was taken on Wednesday, January  
 4 7, 2015, commencing at 1:37 p.m., at 1801 California  
 5 Street, Suite 5100, Denver, Colorado, before Dianna  
 6 L. Buckstein, Professional Shorthand Reporter and  
 7 Notary Public within and for the State of Colorado.

8

9

## 10 I N D E X

11

## 12 DEPOSITION OF BRIAN FLYNN

## 13 EXAMINATION BY:

## PAGE

14 Mr. Kuntz 5, 266, 269

15 Mr. Snell 235, 268, 271

16 Mr. Koopmann --

17

## 18 EXHIBITS

## INITIAL REFERENCE

19 Exhibit 1 Rule 26 Expert Report 20  
 of Brian J. Flynn

20

Exhibit 2 Plaintiff's Second 42

21 Amended Notice of Oral  
 and Videotaped Deposition

22 of Defendant Johnson &  
 Johnson and Ethicon, Inc.'s  
 23 Expert Brian J. Flynn, M.D.

24 Exhibit 3 Chart of billing that 44  
 totals \$10,200.00

25

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	EXHIBITS	INITIAL REFERENCE
1	Exhibit 4	Article entitled Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia
2		52
3		
4		
5		
6		
7	Exhibit 5	Master Consulting Agreement
8		96
9	Exhibit 6	Black binder
10		96
11	Exhibit 7	Black binder labeled Records: Dr. Luu and Dr. Allen
12		96
13	Exhibit 8	Orange folder of documents
14		96
15	Exhibit 9	Black binder labeled Dr. Allen Deposition
16		96
17	Exhibit 10	Black binder labeled TVT-O Company Docs
18		96
19	Exhibit 11	Black binder labeled TVT-R RCTs
20		96
21	Exhibit 12	Black binder labeled TVT-R Materials
22		96
23	Exhibit 13	Black binder labeled Ethicon Pelvic Mesh Litigation
24		96
25	Exhibit 14	Black binder
	Exhibit 15	Black binder
	Exhibit 16	Black binder labeled SUI Medical Literature
		96
	Exhibit 17	Black binder labeled TVT Company Docs

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	EXHIBITS	INITIAL REFERENCE
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2	Exhibit 18 Black binder labeled	96
3	TVT-O RCTs	
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5	Mathur, M.D.	
6	Exhibit 20 Deposition of Eric	96
7	Rovner, M.D.	
8	Exhibit 21 CD labeled Ethicon	96
9	Pelvic Mesh Litigation	
10	Exhibit 22 CD labeled Gyne-mesh:	96
11	Medical Literature;	
12	SUI	
13	Exhibit 23 CD labeled Mesh Materials	96
14	Exhibit 24 CD labeled Ethicon	96
15	Gynecare Pelvic Mesh	
16	Litigation	
17	Exhibit 25 Silver thumb drive	96
18	Exhibit 26 Handwritten notes	96
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20	Flynn, Brian - Materials	
21	List.XLSX, Medical	
22	Literature	
23	Exhibit 28 Black thumb drive	96
24	Exhibit 29 Document entitled	192
25	Anatomy	
	Exhibit D1 Brian J. Flynn, MD,	236
	Summary of Opinions	
	Exhibit D2 IME report by	237
	Brian J. Flynn, M.D.	

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1 P R O C E E D I N G S

2 BRIAN FLYNN, M.D.,

3 being first duly sworn in the above cause, was  
4 examined and testified as follows:

5 EXAMINATION

6 BY MR. KUNTZ:

7 Q Doctor, state your full name for the  
8 record, please.

9 A I'm Dr. Brian Joseph Flynn, M.D.

10 Q And where do you currently work?

11 A I work for the University of Colorado at  
12 Denver.

13 Q And you understand we're here to talk today  
14 about the TVT Abbrevo as it related to Coleen Perry,  
15 correct?

16 A Correct.

17 Q And you currently don't use the TVT  
18 Abbrevo, right?

19 A Incorrect.

20 Q Okay. When did you start using the TVT  
21 Abbrevo after you stopped for a brief period of time?

22 MR. SNELL: Objection to form.

23 A I don't remember ever stopping. I've used  
24 the TVT Abbrevo starting in 2011.

25 Q (By Mr. Kuntz) And you use it currently?

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1           **A**     It's one of the many procedures I perform  
2     for stress incontinence, yes.

3           **Q**     How many did you put in in the year 2014?

4           **A**     I don't recall an exact number.

5           **Q**     Well, give me your best estimate.

6           **A**     Less than five.

7           **Q**     Okay. How many did you put in in 2013?

8           **A**     2013, probably around 10.

9           **Q**     Okay. What about 2012?

10          **A**     2012, at least 25.

11          **Q**     Okay. And 2011?

12          **A**     That was my most common procedure in '11.  
13     Probably around 50 or so.

14          **Q**     Why have you decreased your use of the TVT  
15     Abbrevio?

16          **A**     I find the efficacy, meaning the success  
17     rate of the procedure, in terms of dry rates are  
18     higher with retropubic tapes in patients with  
19     intrinsic sphincter deficiency, which accounts for a  
20     large percentage of my patients.

21          **Q**     So you believe the TVT Retropubic product  
22     works better as far as efficacy and success rates?

23                   MR. SNELL: Form. It misstates.

24          **A**     Can you repeat the question?

25          **Q**     (By Mr. Kuntz) Yeah. Tell the jury what

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1 "efficacy" means, Doctor.

2 **A** Efficacy means the effectiveness -- the  
3 cure rate. So it's a number that reports the good  
4 side of the outcome, how many people are dry by the  
5 procedure.

6 **Q** And you use the TVT Retropubic device now  
7 because you believe the cure rate is better than for  
8 -- than the TVT Abbrevio?

9 MR. SNELL: Objection, form. It misstates.

10 **A** I believe that it has a higher success rate  
11 in terms of dry rates. So in a patient with  
12 intrinsic sphincter deficiency, which is a more  
13 severe type of stress urinary incontinence, which  
14 accounts for a large percentage of my patients,  
15 that's my preferred procedure.

16 **Q** (By Mr. Kuntz) How many TVT-Os did you  
17 implant in 2014?

18 **A** Meaning the TVT Obturator product?

19 **Q** Correct.

20 **A** Zero.

21 **Q** Okay. How many TVT-Os did you implant in  
22 2013?

23 **A** Zero.

24 **Q** How many TVT-O products did you implant in  
25 2012?

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1           **A**       Zero.

2           **Q**       Is there a reason that you no longer use  
3       the TVT-O, Obturator, product?

4           **A**       I prefer the TVT Abbrevio over the TVT  
5       Obturator. So once I started using TVT Abbrevio, I  
6       stopped using TVT Obturator.

7           **Q**       And why do you prefer using the TVT Abbrevio  
8       over the Obturator?

9           **A**       The procedure is very similar, and I find  
10       it to be easier to perform, less trauma to the  
11       tissue. You don't have to perforate the obturator  
12       membrane with the wing guide, and it leaves less mesh  
13       in either leg. Probably about 3 centimeters less  
14       mesh in each hemipelvis. So you leave about  
15       6 centimeters less mesh in the patient.

16          **Q**       Why is it important to have less mesh left  
17       in the patient after a mesh procedure?

18                   MR. SNELL: Form.

19          **A**       I think you want to have the optimal amount  
20       of mesh, just enough to cure the problem but not too  
21       much that you create other problems.

22          **Q**       (By Mr. Kuntz) What other problems do you  
23       create if there's too much mesh left in the patient?

24          **A**       Well, there could be a number of issues.  
25       Primarily it occurs with prolapse kits, transvaginal

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1 for instance, but if the mesh overlaps or the mesh is  
2 bunched, it won't incorporate into the patient, so it  
3 won't become part of them.

4 Q Any other problems that can occur if too  
5 much mesh is left in the patient after a mesh  
6 procedure?

7 A Well, you can have sequela from the mesh  
8 not incorporating.

9 Q And why -- what are the reasons why mesh  
10 cannot incorporate? What causes that?

11 A There's a variety of factors, but the one  
12 that I've seen primarily in my own practice is mesh  
13 overlapping, so if the mesh is not lying flat. If  
14 you have mesh lying on mesh, then there's no  
15 surrounding native tissue to grow into the pores.

16 Q Before getting involved in this litigation  
17 as a consultant, did you know that Ethicon sold the  
18 TVT Obturator in both mechanical-cut mesh and  
19 laser-cut mesh?

20 A Yes. I've been using the Ethicon products  
21 since I started in practice, and I've used both  
22 products.

23 Q And how did you know what product you were  
24 using was either laser-cut mesh or mechanical-cut  
25 mesh?

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1           **A**       Well, a number of ways. First off, it's  
2       labeled. So if you look at the box, say, for classic  
3       TVT, when they started offering classic TVT as  
4       laser-cut, the last number would end in the letter L  
5       to signify that it was laser-cut.

6                    Additionally, when it got ordered, you were  
7       asked which product you'd want to order. So when you  
8       had your person in the OR doing the ordering, they  
9       would ask you that.

10                   Also, you were detailed by the salesperson  
11       in your area, and then certainly when you have the  
12       mesh in your hand, you can look and feel some subtle  
13       differences.

14           **Q**       So it's your testimony that -- let me ask  
15       you this: Do you -- you believe that when you hold  
16       the mesh in your hand, you can tell a difference  
17       between the laser-cut mesh and the mechanical-cut  
18       mesh?

19           **A**       I can.

20           **Q**       Okay. Do you believe -- have you ever  
21       talked to doctors who've told you that they could not  
22       find a difference in the mesh?

23                   MR. SNELL: Foundation, form.

24           **Q**       (By Mr. Kuntz) Let me ask you this,  
25       Doctor: Have you ever told Ethicon that if you

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1 change the mesh, that doctors wouldn't know the  
2 difference?

3 **A** I've never said a statement like that, no.

4 **Q** Okay. You understand you're under oath  
5 today, and you've never made that statement? That's  
6 your testimony today?

7 **A** Why don't you repeat the question so we're  
8 clear.

9 **Q** Have you ever told Ethicon that if you  
10 changed the mesh, doctors would not know the  
11 difference?

12 MR. SNELL: Form. Go ahead.

13 **A** I don't -- I don't believe I ever said that  
14 statement.

15 **Q** (By Mr. Kuntz) Okay. How many of the  
16 TVT-O meshes that you've placed in your career were  
17 laser-cut mesh versus mechanical-cut mesh?

18 **A** I would be approximating, but I used TVT-O  
19 from 2004 to the time that TVT Abbrevio came out,  
20 around 2010, 2011, and I believe laser-cut mesh was  
21 offered in and around 2007 or '8.

22 So I would say for half of the time of  
23 that, you know, eight years -- seven or eight years  
24 that I was doing TVT-O, half of them were laser-cut,  
25 half were mechanically-cut.

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1           **Q**     Do you know that number for sure?

2           **A**     I'm just going by years. So, you know,  
3     some years I might have done more procedures than  
4     other years, but if I'm just counting number of  
5     years, then that would be my best approximation.

6           **Q**     And it's your testimony that when you were  
7     ordering the laser-cut mesh -- strike that.

8                     It's your testimony that when you were  
9     ordering TVT Obturator products, you could choose on  
10    the form whether you wanted laser-cut mesh or  
11    mechanical-cut mesh?

12          **A**     I could direct the people who did the  
13    ordering to -- to order what I would like to have,  
14    yes.

15          **Q**     And what did you tell them that you would  
16    like to have when you were ordering your TVT  
17    Obturator products?

18          **A**     I told them I would like to use the  
19    laser-cut mesh.

20          **Q**     So you prefer the laser-cut mesh over  
21    mechanical-cut mesh in the TVT Obturator product?

22          **A**     Correct.

23          **Q**     And why do you prefer laser-cut mesh over  
24    mechanical-cut mesh?

25          **A**     There's a --

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1 MR. SNELL: Form. Go ahead.

2 A There's a number of reasons, but primarily  
3 I like the tissue-handling -- I should say the mesh-  
4 handling characteristics better. It -- it's easier  
5 to deploy, and the ends are nontanged, which means  
6 that they're sealed so there's less fraying at the  
7 edges.

8 Q (By Mr. Kuntz) Anything else?

9 A I believe that it maintains its form or  
10 integrity better, so there's less deformation of the  
11 laser-cut mesh.

12 Q Anything else?

13 A I think it's a little bit easier to see. I  
14 think the color blue is a little bit brighter for  
15 whatever reason on the laser-cut mesh.

16 Q Okay. Anything else?

17 A There may be something else I'm leaving  
18 out, but those are the things that come to me  
19 immediately.

20 Q You have said that your detail person --  
21 which is -- for the jury's standpoint means sales  
22 rep, correct?

23 A That's correct.

24 Q Okay. You said your detail person at  
25 Ethicon had told you or informed you about Ethicon's

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1 decision to sell laser-cut mesh and mechanical-cut  
2 mesh. Is that your testimony?

3 MR. SNELL: Form. Misstates the prior  
4 testimony.

5 Q (By Mr. Kuntz) Well, let me ask you this:  
6 You said you learned about laser-cut mesh from your  
7 detail person. Isn't that what you testified to,  
8 Doctor?

9 MR. SNELL: Same objection, form. It  
10 misstated the testimony.

11 A He was one of many people. There's other  
12 people that informed me.

13 Q (By Mr. Kuntz) Okay. Who were the other  
14 people that informed you?

15 A People within the company.

16 Q And who were those people?

17 A People in professional education, my local  
18 sales person's manager and his manager.

19 Q Who are the people within the company that  
20 informed you? Give me a name.

21 A Well, the sales person -- I'm guessing --  
22 around 2007 or '8 would have been John Fernandez or  
23 Laura Hutto. And then their manager was Marcus  
24 Olderler. Scott Jones is another person I know.

25 Q Who's Scott Jones?

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1           **A**       Scott Jones was also involved in  
2 professional education.

3           **Q**       Was Scott Jones a national sales rep or  
4 national sales leader for Ethicon?

5           **A**       I've known Scott in a lot of different  
6 capacities. He initially -- I knew him first when he  
7 was the sales rep in Denver in and around 2004, and  
8 then he became a regional manager, and then I believe  
9 he moved into professional education.

10          **Q**       I mean, you'd agree he's a higher-up at  
11 Ethicon now or was?

12                   MR. SNELL: Form, vague. Go ahead.

13          **A**       Can you explain to me what you mean by  
14 "higher-up."

15          **Q**       (By Mr. Kuntz) Well, I mean, he's in upper  
16 management at Ethicon, correct?

17          **A**       He -- he did, you know, advance to those  
18 positions. I don't know what his position is now,  
19 but at least the last time I had contact with him, he  
20 was in upper management.

21          **Q**       Okay. Do you suspect -- or strike that.

22                   Do you expect your detail person or sales  
23 rep, as a practicing physician using Ethicon's  
24 products, to inform you about things like difference  
25 in the cuts of the mesh?

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1 MR. SNELL: Form, vague. Go ahead.

2 A I expect them to be familiar with the  
3 products that they're offering to me.

4 Q (By Mr. Kuntz) Do you know if Dr. Luu, in  
5 this case, was told -- ever told about a difference  
6 between laser-cut mesh and mechanical-cut mesh?

7 A I know that he went to a cadaver lab to  
8 learn about the procedure. I can't say definitively  
9 whether or not that was brought up with him, but if  
10 he was paying attention at the lab, I'm sure he would  
11 have become aware of it.

12 Q Do you know what lab he went to?

13 A I don't know the exact lab, but I know that  
14 he did go to a cadaver lab. That's pretty standard  
15 when people start doing new procedures, if they're  
16 not familiar with them.

17 Q But as you sit here today, you don't know  
18 whether he knew the difference between laser-cut mesh  
19 and mechanical-cut mesh, correct?

20 MR. SNELL: Form and foundation as to  
21 "difference." Go ahead.

22 A I reviewed his deposition, and I can't say  
23 either way. I don't remember him being asked that  
24 question.

25 Q (By Mr. Kuntz) Have you read the sales

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1 rep's deposition in this case?

2 **A** I don't know who the sales rep is. So no,  
3 I don't believe I've read their deposition.

4 **Q** So that was a deposition that was not  
5 provided to you by Ethicon's attorneys, correct?

6 **A** You might have to say the name, or I can  
7 tell you the depositions. I'll just give you a list  
8 of the ones that were provided to me.

9 **Q** Okay. Go ahead and give me a list.

10 **A** This is just off the top of my head. I  
11 don't have it in front of me, but it is on the thumb  
12 drive.

13 I've reviewed the depositions of Coleen  
14 Perry; her husband, Mr. Perry. I've reviewed the  
15 deposition of Dr. Margolis, Dr. Rosenzweig, Dr. Helm,  
16 Dr. Allen, Dr. Luu, I believe Dr. Singh, Dr. Marthur.  
17 I've reviewed Dr. Guelcher -- I believe he's a  
18 physician -- Guelcher -- at Vanderbilt University --  
19 Doug Grier -- Dr. Doug Grier.

20 There may be a few others that I'm leaving  
21 out, but those are the ones that immediately come to  
22 mind.

23 **Q** Have you read any depositions of any of the  
24 Ethicon corporate employees?

25 **A** I don't believe so.

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1           **Q**     Okay. Do you know if you were provided  
2     with any depositions of any of the corporate  
3     employees from Ethicon?

4           **A**     Not in this case.

5           **Q**     Okay. What case have you reviewed those  
6     depositions?

7           **A**     I was involved in the Lewis case, and I  
8     would have to go back and look at my notes, but I  
9     believe I may have reviewed a deposition from the  
10    Lewis case, but I'm not certain.

11          **Q**     Okay. You can agree with me that none of  
12    the depositions -- well, strike that.

13               None of the corporate Ethicon depositions  
14    formed the basis for any of your opinions in this  
15    case, correct?

16          **A**     That's correct.

17          **Q**     In speaking of the Lewis case, you -- have  
18    you reviewed your report that you submitted in  
19    federal case for the Lewis case recently?

20          **A**     I have, and I have it in front of me here.

21          **Q**     Okay. And you still stand by every  
22    statement you make in that report, correct?

23          **A**     I would have to go through each individual  
24    statement, but I'm very comfortable with that  
25    document.

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1           **Q**     Okay. Well, you reviewed it recently to  
2     prepare for this deposition, didn't you?

3           **A**     I did. I read it this morning and last  
4     evening.

5           **Q**     Okay. And there was nothing that stood out  
6     that you wanted to correct or change or felt was  
7     inappropriate, correct?

8                   MR. SNELL: Form, compound. Go ahead.

9           **A**     I would like to have a minute just to look  
10    at that real quick before I make the answer to that  
11    question. So I'm opening up my folder here.

12                  MR. SNELL: You can take your time to look  
13    at it, if you need to look at it. It's not a memory  
14    test.

15                  Can we go off the record? I've just got to  
16    go use the restroom while he's reading or looking at  
17    this report.

18                  MR. KEITH: We're going to go off the  
19    record, Jeff.

20                  MR. KUNTZ: That's fine.

21                         (Recess from 1:58 p.m. to 1:59 p.m.)

22                  MR. KUNTZ: Let's go ahead and mark -- mark  
23    the Carolyn Lewis report as Exhibit No. 1.

24                  MR. KEITH: There's another exhibit sticker  
25    on it. Do you want me to go over the top of it or to

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1 the side of it? Does anybody have any suggestions?

2 MR. KUNTZ: You can go over it. It doesn't  
3 matter.

4 MR. SNELL: Yeah, I don't care. Just put  
5 it over it.

6 (Exhibit 1 was marked.)

7 MR. KEITH: Okay. It's been marked as  
8 Exhibit 1.

9 MR. KUNTZ: We're back on the record,  
10 right?

11 MR. KEITH: That's correct.

12 Q (By Mr. Kuntz) Dr. Flynn, you have  
13 reviewed what has been marked Exhibit 1, which is  
14 your Rule 26 Expert Report in the Carolyn Lewis case,  
15 and you've had a chance to review that, correct?

16 A Correct.

17 Q Okay. And is there any -- do you stand by  
18 all the statements that have been made in this  
19 report?

20 A No.

21 Q Okay. What would you like to change about  
22 this report?

23 A On Page 3, Section B, like in boy, the very  
24 last sentence, it says, "Currently I use TVT Exact  
25 and TVT Obturator for the treatment of stress

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1     incontinence." That statement is not correct today.  
2     It wasn't correct then.

3           **Q**     Okay. And I take it you reviewed that  
4     report several times before putting your signature at  
5     the back of it and filing it in federal court,  
6     correct?

7           **A**     Correct.

8           MR. SNELL: Form and foundation, "filed."

9           **Q**     (By Mr. Kuntz) And tell me now what you  
10    want to change about that statement.

11          **A**     It should say, "Currently I use the TVT  
12    Exact and TVT Abbrevio for treatment of stress  
13    incontinence."

14          **Q**     Okay. Did you have help writing this  
15    report in the Carolyn Lewis case?

16          MR. SNELL: Form. Don't answer that.  
17    Jeff, we have an agreement we don't ask those  
18    questions in the federal court. You know that.

19                 I'm going to instruct the witness -- I'm  
20    not going to let him answer that. I don't ask --

21                 (All speaking simultaneously.)

22          MR. SNELL: I don't ask Margolis and your  
23    experts about --

24          MR. KUNTZ: Hey, Burt, calm down. It was a  
25    mistake. I agree.

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1 MR. SNELL: Okay.

2 THE DEPONENT: I'm not going to answer that  
3 question.

4 MR. KUNTZ: I withdrew the question.

5 MR. SNELL: He withdrew it.

6 THE DEPONENT: All right.

7 Q (By Mr. Kuntz) So at the time of that  
8 report, you used the Exact and the TVT Abbrevio; you  
9 did not use the TVT Retropubic or the TVT Obturator?

10 A The word "Retropubic" is confusing, but TVT  
11 Exact is a retropubic. You may hear me today use  
12 those words interchangeably, but TVT Classic and TVT  
13 Exact are both retropubic tapes.

14 Q And I understand that, Doctor. Which one  
15 of them do you use today?

16 A I see. I use the TVT Exact.

17 Q Okay. When is the last time you used the  
18 TVT Retropubic?

19 A Well, again, the TVT Exact is a retropubic.  
20 Are you referring to TVT Classic?

21 Q Right. Let me clarify this.

22 There's no such thing as the TVT Classic,  
23 Doctor. There's a TVT Retropubic; there's the TVT  
24 Exact; there's a TVT Obturator and the TVT Abbrevio.

25 I know people have put the term "Classic"

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1 on the Retropubic, but I guess we can use  
2 "Retropubic" and "Classic" interchangeably.

3 And my question is: When did you stop  
4 using the TVT Retropubic or Classic?

5 **A** That would be when I started using the TVT  
6 Exact. So I was probably the first person in  
7 Colorado to use the TVT Exact product.

8 I believe that was sometime around 2011 or  
9 2012. I don't remember the exact year, but when I  
10 started using Exact, I stopped using Retropubic.

11 **Q** Okay. In your Lewis report, you also state  
12 up until 2012, that you performed 900 stress urinary  
13 incontinence procedures.

14 Do you see that in the report?

15 **A** I do.

16 **Q** And it also states that you used -- you  
17 performed 535 TVT procedures between 2006 and 2012.  
18 Do you see that?

19 **A** Yes.

20 **Q** So what are the other 365 procedures?

21 **A** You want me to name all of them?

22 **Q** Yes.

23 **A** Okay. So I'll use autologous rectus fascia  
24 pubovaginal sling. Allograft pubovaginal sling, so  
25 that's Procedure No. 2.

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1 I use -- artificial urinary sphincter would  
2 be No. 3. I also use transurethral bulking agents.  
3 Specifically Macroplastique is a product I use. And  
4 Burch colposuspension. Very few cases, but I have  
5 done that. That would be included in that other  
6 number.

7 And when I speak to TVT procedures, that's  
8 -- probably 500 out of the 535 are the Ethicon  
9 product. There's probably part of that 535 that was  
10 from some of the other manufacturers.

11 Q Okay. And what other manufacturers'  
12 products do you use or have you used?

13 A American Medical Systems, Boston --

14 Q Which products?

15 A From American Medical Systems --

16 Q Yes.

17 A -- I have used Sparc, Monarc, RetroArc, and  
18 MiniArc with -- are you speaking specifically to  
19 incontinence?

20 Q Yeah. Let's keep it at that.

21 A Yes.

22 Q Have you used any Bard products?

23 A I don't believe I've ever used any Bard  
24 products.

25 Q Have you ever used any Boston Scientific

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1 products?

2 **A** I have, and I still do.

3 **Q** Which one?

4 **A** I use the Boston Scientific Advantage Fit.

5 **Q** Anything else --

6 **A** No --

7 **Q** -- I --

8 **A** -- not for --

9 (All speaking simultaneously, and reporter  
10 requested clarification.)

11 MR. KEITH: Say that again, Jeff.

12 **Q** (By Mr. Kuntz) Anything else for SUI  
13 treatments?

14 **A** Nothing else for SUI treatments from Boston  
15 Scientific.

16 **Q** Is the MS Monarc product laser cut, Doctor?

17 **A** I don't know the answer to that. I've used  
18 the American Medical Systems' products sparingly, so  
19 I'm not as familiar with those products.

20 **Q** Is the MiniArc -- do you know if any of the  
21 products, the Sparc, Monarc, or MiniArc, are  
22 laser-cut mesh?

23 **A** Just looking at them, I don't believe they  
24 are, but I don't know those products as well as I  
25 know the Ethicon products.

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1           **Q**     Have you ever consulted for AMS?

2           **A**     I have.

3           **Q**     Okay. What years did you consult for them?

4           **A**     From around 2004 to 2010.

5           **Q**     You never consulted with them after 2010?

6           **A**     For female urology products?

7           **Q**     Correct.

8           **A**     Not for female urology. I never really  
9           consulted for female urology. I was more of a  
10          consultant on the male side.

11          **Q**     Did you ever receive payments or  
12          reimbursements or any type of money from AMS after  
13          2010?

14          **A**     I would have to go back and look at my  
15          records, but I think two thousand -- either '10 or  
16          2011 -- one of those two years was when I ended my  
17          relationship with them.

18          **Q**     Do you keep records on your relationships  
19          -- your consulting relationships with these different  
20          manufacturers?

21          **A**     I keep some records, you know, for recent  
22          years for tax purposes, but I don't -- I don't keep  
23          all of my records. No. I hang on to important  
24          documents that I give to my accountant, recent  
25          documents.

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1           **Q**     Okay. But you do keep some of the  
2 documents?

3           **A**     I do keep some of the documents, yes.

4           **Q**     And you keep those on your computer or in a  
5 hard file?

6           **A**     Either/or.

7           **Q**     Okay. Did you bring any of those documents  
8 with you today?

9           **A**     I was able to find one contract, but that  
10 wasn't a contract with American Medical Systems.  
11 Most contracts I've received came in paper form, not  
12 electronic form.

13          **Q**     Okay. Do you keep those paper documents?

14          **A**     I went through everything in the last few  
15 days, and what I've brought in to today's deposition,  
16 I could only find one contract, and I do have that  
17 with me today.

18          **Q**     Did you find any contracts that you have  
19 with Ethicon?

20          **A**     Yes. That's the contract I'm speaking of.  
21 I couldn't locate anything from AMS or any of the  
22 other venders.

23          **Q**     Okay. And we'll get into that in a little  
24 bit.

25                   Do you keep other documents on your

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1 computer?

2 **A** Can you be more specific?

3 **Q** Well, do you -- you obviously keep all the  
4 e-mails that you have between Ethicon and Johnson &  
5 Johnson and your role as a consultant with them,  
6 correct?

7 MR. SNELL: Foundation, form. It  
8 misstates.

9 **A** I keep very little in e-mail. You know, I  
10 respond to an e-mail, but I don't -- I don't archive  
11 e-mails.

12 **Q** (By Mr. Kuntz) Okay. So you don't keep a  
13 folder of any e-mails of -- you don't have a folder  
14 that says "Ethicon Consulting," and you don't keep  
15 any of those e-mails anywhere?

16 **A** I have a folder -- a folder, and I clear  
17 out my folders periodically. And I have brought all  
18 e-mails that I have from Ethicon, and that is on the  
19 USB. It's in a folder listed "e-mails," and there's  
20 about 20 e-mails in that folder.

21 **Q** How far back do those e-mails go? To what  
22 year? Is that just for the last year?

23 **A** It goes back to around 2012 or so.

24 **Q** Okay.

25 **A** That's an approximate date. It's about

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1 two, maybe three years of e-mails.

2 Q Do you have a consultant agreement with  
3 Ethicon in 2012?

4 A I don't believe so.

5 Q Did you have a consultant agreement with  
6 Ethicon in 2013?

7 A No.

8 Q Do you currently have a consulting  
9 agreement with them?

10 A I do not.

11 Q Do you have a current -- do you currently  
12 have a consulting agreement with any mesh  
13 manufacturer?

14 A I do not.

15 Q Why is that? I mean, did you stop -- why  
16 did you stop deciding to consult with mesh  
17 manufacturers?

18 MR. SNELL: Form and foundation. It  
19 misstates. Go ahead.

20 A It was a mutual decision on both parties.  
21 There just wasn't enough activity for it to really be  
22 something that was interesting to me at that point.

23 Q (By Mr. Kuntz) And --

24 A So Ethicon, American Medical Systems,  
25 others, their prof ed events had decreased

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1 significantly to the point that it really wasn't  
2 anything that I was interested in doing anymore.

3 Q Do you -- did you ever ask Ethicon why they  
4 withdrew you as an expert in the Carolyn Lewis case?

5 A I did.

6 Q Okay. And what were you told?

7 MR. SNELL: I'm going to object. He's not  
8 allowed to answer that, Jeff. We're not going to --

9 MR. KUNTZ: I don't --

10 MR. SNELL: Again, Jeff, you're doing stuff  
11 that we agree we don't do. We don't talk about  
12 communications. I'm frankly, you know, shocked that  
13 you're asking this.

14 MR. KUNTZ: Oh, Burt. Give it up.

15 MR. SNELL: Well, I'm going to instruct him  
16 not to answer. You know I'd never ask your people of  
17 that. People would have -- they would have a --

18 MR. KUNTZ: -- never withdrew --

19 MR. SNELL: -- heart attack.

20 MR. KUNTZ: -- any of them.

21 MR. SNELL: Yes, you have.

22 MR. KUNTZ: So --

23 MR. SNELL: Yes, you have.

24 MR. KUNTZ: -- feel free to ask.

25 (All speaking simultaneously.)

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1           **Q**       (By Mr. Kuntz) When were you first trained  
2 on the TVT-O procedure by Ethicon?

3           **A**       When or where?

4           **Q**       When.

5           **A**       When? When I started using the products.  
6 So I started using the product, you know, early in my  
7 practice, 2004 -- in and around 2004.

8           **Q**       And you became a preceptor for them in two  
9 thousand and -- December of 2004?

10          **A**       I don't know the exact date, but somewhere  
11 in and around 2004.

12          **Q**       And you've authored instructional videos  
13 for Ethicon for the Abbrevio, the Secur, and the  
14 Prolift, correct?

15          **A**       Incorrect.

16          **Q**       Okay. What products have you authored  
17 instructional videos for?

18          **A**       On behalf of Ethicon, just Abbrevio. I do  
19 have videos on the other products, but they were for  
20 scientific meetings, not for Ethicon.

21          **Q**       So did you prepare instructional videos for  
22 scientific meetings for Secur and Prolift?

23          **A**       Yes.

24          **Q**       And what meetings did you prepare those  
25 for?

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1           **A**       They were presented at a variety of  
2       meetings.

3           **Q**       Well, which ones?

4           **A**       American Urologic Association, the south  
5       central section of the American Urologic Association,  
6       I would have to go back and look at my CV, but I know  
7       at least at those two meetings.

8           **Q**       And you understand that the Secur and the  
9       Prolift are off the market?

10          **A**       I understand that those products are no  
11       longer being offered.

12          **Q**       Okay. What is your understanding as to why  
13       those products are no longer being offered?

14          **A**       I believe it was a business decision that  
15       Ethicon made. They weren't popular products.

16          **Q**       Did you ever ask or have any discussions  
17       with Ethicon why they decided to quit selling those  
18       products?

19          **A**       You'd have to separate the two products.

20          **Q**       Okay. Did you ever have discussions with  
21       Ethicon why they stopped selling the TVT Secur?

22          **A**       Yes.

23          **Q**       What were those conversations?

24          **A**       That the product just was not a popular  
25       product amongst their providers, and so they were

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1 going to discontinue it.

2 Q Anything else a part of those  
3 conversations?

4 A I believe that the FDA had mandated 522  
5 studies on mini slings, and TVT Secur was included in  
6 that, and that that wasn't something they were going  
7 to pursue.

8 Q Do you know what a 522 order is?

9 A I do.

10 Q Okay. Did you review the 522 order related  
11 to the TVT Secur issued by the FDA?

12 A It wasn't sent to me. I've never seen the  
13 document. I understand 522 concept in general, but  
14 --

15 Q Okay. What's your -- what's -- did you  
16 ever discuss the 522 concept with Ethicon?

17 A No.

18 Q Did they ever send you information related  
19 to the 522 orders?

20 A No.

21 Q What is your understanding as to what a 522  
22 order is?

23 A 522 study is a rigorous scientific study of  
24 a product. It's something that the federal  
25 government mandates certain devices in certain

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1 categories. So you have different categories of  
2 devices, and if a device is in, say, Category B, then  
3 they need 522s. If it's in the -- another category  
4 may be a 510(k) study or process.

5 Q Did you ever review Ethicon's response to  
6 the 522 order?

7 A I don't believe so.

8 MR. SNELL: Form -- hold on. Form, vague  
9 as to the product you're referencing, Jeff.

10 Q (By Mr. Kuntz) Have you ever reviewed  
11 Ethicon's response on the TVT Secur to the 522 order  
12 issued by the FDA?

13 A No.

14 Q Have you ever seen any letters or responses  
15 between Ethicon and the FDA related to the 522 orders  
16 on the TVT Secur?

17 A No.

18 Q Did you ever ask Ethicon to see anything  
19 related to the 522 orders on the TVT Secur and their  
20 response?

21 A No.

22 Q Do you know what studies that Ethicon  
23 proposed or submitted in response to the 522 order on  
24 the TVT Secur to the FDA?

25 A I don't know, no.

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1           **Q**     Do you have any idea what the FDA told  
2     Ethicon about the adequacy of the studies they  
3     submitted in response to the 522 order for the TVT  
4     Secur?

5                   MR. SNELL:   Foundation.   Go ahead.

6           **A**     No.

7           **Q**     (By Mr. Kuntz)   Same questions on the  
8     Prolift.   Did you ever review the 522 order issued to  
9     Ethicon on the Prolift?

10          **A**     No.

11          **Q**     Did you ever ask or did Ethicon ever show  
12     you any of their responses to the 522 orders on the  
13     Prolift?

14          **A**     No.

15          **Q**     Did you ever ask to see or do you know of  
16     any of the studies that Ethicon submitted to the FDA  
17     in an attempt to satisfy the 522 order on the  
18     Prolift?

19          **A**     No.

20          **Q**     How many TVT Securs did you implant before  
21     they went off the market?

22          **A**     More than 100.

23          **Q**     When's the last time you used the TVT  
24     Secur, if you know?

25          **A**     Probably in and around 2010 or 2011.

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1           **Q**     How did you know that the TVT Abbrevio uses  
2     laser-cut mesh?

3           **A**     A number of ways. It's labeled on the box  
4     with the letter L, like I mentioned earlier.  
5     Information from the sales rep and from the people in  
6     professional education, from attendance at cadaver  
7     labs in being faculty in those events, from  
8     instructing other physicians on TVT Abbrevio, I was  
9     very familiar with the product.

10          **Q**     Is it your testimony that the TVT Abbrevio  
11     is marked with an L on the product ID sticker?

12          **A**     I would have to look at that. I know it is  
13     for the Retropubic and the Exact, I think, because  
14     the products were being offered in both forms.

15          **Q**     Okay.

16          **A**     I want to take that back. I don't know for  
17     sure. I'm speaking more to the Retropubic  
18     procedures. So I don't know with 100 percent  
19     confidence if the Abbrevio has the L on the box.

20          **Q**     So if the L is not on the box for TVT  
21     Abbrevio, a doctor, looking at that box before it  
22     performed a TVT Abbrevio procedure, would not  
23     necessarily know that it was laser-cut mesh?

24                   MR. SNELL: Objection, lacks foundation --

25          **A**     I would --

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1 MR. SNELL: -- improper hypothetically. Go  
2 ahead.

3 A I would disagree with that.

4 Q (By Mr. Kuntz) And why?

5 A Well, like I mentioned earlier, there's  
6 many ways of communicating information. The letter L  
7 on the box was just one of many ways. Other ways  
8 would be through the sales person, through attendance  
9 at professional educational events, from reading the  
10 IFU.

11 So a physician has a responsibility to  
12 obtain as much information as he or she can on a  
13 product before using it.

14 Q Dr. Flynn, does the TVT Abbrevio IFU state  
15 that it's laser-cut mesh?

16 A I would have to have the IFU in front of  
17 me.

18 Q So as you sit here -- let me ask you this:  
19 Did you review the IFU in preparation for this  
20 deposition today?

21 A I did.

22 Q Okay. And you teach Abbrevio preceptor or  
23 cadaver lab courses?

24 A I did.

25 Q But you don't know, as you sit here right

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1 now, one way or another, whether the TVT Abbrevio IFU  
2 states that the mesh is laser cut, correct?

3 **A** Correct.

4 **Q** Okay. And you don't know if the box that  
5 the TVT Abbrevio comes in states that it's laser-cut  
6 mesh?

7 **A** That's correct.

8 **Q** And you can't tell me that every cadaver  
9 lab or preceptorship or meeting -- that physicians  
10 are told that the Abbrevio was laser cut as you sit  
11 here today?

12 **A** I can tell you the ones that I attended and  
13 the ones that I instructed and lectured on, certainly  
14 they were told, but I can't speak of labs that I  
15 didn't attend.

16 **Q** And you never attended, to your knowledge,  
17 any classes that Dr. Luu was present at with regard  
18 to either the TVT Abbrevio -- with the TVT Abbrevio?

19 **A** I've never met Dr. Luu in any capacity, so  
20 no.

21 **Q** Ever talk to Dr. Luu?

22 **A** No.

23 **Q** Ever talk to Dr. Allen, who's involved in  
24 this case?

25 **A** No.

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1           **Q**     Ever talk to Dr. Grier about his expert  
2     opinions in this case?

3           **A**     I spoke to Dr. Grier last night.

4           **Q**     Okay. What did you guys talk about?

5           **A**     He called me to wish me good luck.

6           **Q**     Okay. Do you talk to him often?

7           **A**     A few times a year, three or four times a  
8     year.

9           **Q**     Did you talk -- did you ever talk to  
10    Dr. Grier about the IME you performed on Mrs. Perry?

11          **A**     No.

12          **Q**     Did you work on -- you provided a Summary  
13    of Opinions sheet in this case. You understand that  
14    that lists 25 or 26 opinions?

15          **A**     Yes, I have that document in front of me.

16          **Q**     Did you prepare that yourself?

17          **A**     You would have to be more specific.

18          **Q**     Did you prepare the Summary of Opinions  
19    sheet by yourself? Did you write those opinions  
20    yourself, or did you receive help from counsel?

21                 MR. SNELL: I'm going to object and  
22    instruct not to answer. I don't think we're doing  
23    that here again, Jeff.

24          **Q**     (By Mr. Kuntz) Okay. Did you -- did you  
25    prepare your report with Dr. Grier, your Summary of

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1 Opinions report?

2 **A** No. I had seen Dr. Grier's Summary of  
3 Opinions report before I prepared mine, so I was  
4 aware of his, but we didn't directly communicate  
5 about it.

6 **Q** Okay. When did you prepare your Summary of  
7 Opinions report?

8 **A** Yesterday. I had been working on it, you  
9 know, for months, but it was completed yesterday.  
10 I've been working on this probably for six months.

11 **Q** You've been working on preparing for this  
12 deposition for six months?

13 **A** On and off I've been receiving documents,  
14 and I've had communication with Burt Snell over the  
15 last six months.

16 **Q** How many times have you met with Mr. Snell?

17 **A** Face-to-face?

18 **Q** Yes.

19 **A** At least four or five times.

20 **Q** How many times have you talked on the phone  
21 with Mr. Snell?

22 **A** Not including like e-mail or text?

23 **Q** Yes.

24 **A** Probably at least 20 times.

25 **Q** Have you billed every time for those calls

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1 and meetings?

2           **A**     Not for phone calls -- not for most phone  
3 calls. If it was just a phone call to organize a  
4 meeting or to try to connect or find out when we'd be  
5 meeting, you know, I would not. If they were  
6 scheduled -- you know, teleconferences at a scheduled  
7 time and date, yes, I did.

8           **Q**     And we'll get into your billing in a little  
9 bit.

10                   Did you meet with any other lawyers that  
11 are on the defense team for Mrs. Perry's case to  
12 prepare for this deposition in the last six months?

13           **A**     Yes.

14           **Q**     Who else did you meet with?

15           **A**     Barry Koopmann.

16           **Q**     How many times?

17           **A**     Probably similar to Mr. Snell, about the  
18 same number of phone calls and face-to-face  
19 encounters.

20           **Q**     Were those -- was Mr. Snell at these, or  
21 these are separate meetings and phone calls?

22           **A**     The phone calls were sometimes together,  
23 sometimes separate. The face-to-face meetings, I  
24 believe all of them were at the same time.

25           **Q**     Okay.

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1           **A**     So five meetings or so with Burt Snell and  
2     Barry Koopmann. Phone calls -- you know,  
3     organizational phone calls were separate. Scheduled  
4     teleconferences were usually -- at least for a  
5     percentage of the phone call -- at the same time.

6           MR. KUNTZ: I'm going to go ahead and mark  
7     as Exhibit 2 the depo notice. Sean, do you have  
8     that?

9           MR. KEITH: I do.

10          (Exhibit 2 was marked.)

11          MR. KEITH: All right. That's been given  
12     to the witness and counsel.

13          MR. KUNTZ: Okay. It's marked as  
14     Deposition Exhibit No. 2, I believe.

15          MR. KEITH: That's correct.

16          **Q**     (By Mr. Kuntz) Doctor, did you review this  
17     before today?

18          **A**     I have.

19          **Q**     When's the first time you looked at it?

20          **A**     The date I received it.

21          **Q**     Have you gone through and reviewed the  
22     requests in Exhibit A and tried to comply with  
23     Exhibit A?

24          **A**     To the best of my ability, yes.

25          **Q**     Okay. And have you -- obviously, on No. 1,

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1     you provided or brought with you an up-to-date CV?

2           **A**     I do. Do you want me to submit that?

3           **Q**     No. It's fine.

4           **A**     Okay.

5           **Q**     On Request No. 2 -- have you brought all  
6     the documents in your possession, including CDs,  
7     DVDs, and flash drives, and USB drives? It sounds  
8     like you have.

9           **A**     I have CDs. I have DVDs. I have USBs. I  
10    do not have any photographs. I don't have any kind  
11    of data bank.

12                   Expected testimony, I have my Summary of  
13    Opinions. I have my opinions from the Lewis case.  
14    So I believe I complied with No. 2.

15           **Q**     No. 3, it's the same documents that you've  
16    brought to the deposition?

17           **A**     Yes, I have that. Some in paper form; some  
18    in electronic form. There is some overlap between  
19    the paper and the electronic. In efforts to be as  
20    complete as possible, I just brought both.

21           **Q**     Okay. We talked about depositions. I'm  
22    going to jump ahead.

23                   On Request No. 8, have you brought  
24    documents that comply with that request?

25           **A**     I have two time sheets. I have an attached

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1 invoice on one of them. Time sheets and time records  
2 would be the same to me. Billing records -- my only  
3 billing record is the invoice. So that's the same  
4 document.

5 Q And how much -- strike that.

6 What is the bill that you've submitted to  
7 date that you brought with you?

8 A Would you like me to go ahead and submit  
9 that?

10 Q Yeah. Let's go ahead and mark that as  
11 Exhibit No. 3.

12 MR. SNELL: And I'm going to note for the  
13 record that the witness did comply as requested. And  
14 I'm still waiting -- the bills and time sheets from  
15 your experts, Jeff. So I will make that record now.

16 MR. KEITH: This is a two-page -- two  
17 pages, Jeff. I'm going to mark it as Exhibit 3.

18 (Exhibit 3 was marked.)

19 Q (By Mr. Kuntz) How much total time have  
20 you billed to date, Doctor?

21 A Well, what's reflected on those two  
22 documents, there's an invoice time sheet that goes  
23 from July through October, and that is 25 hours. And  
24 then the second invoice -- same exhibit -- is October  
25 and November, and that is 19 hours.

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1 I haven't completed my December time sheet  
2 or invoice or January.

3 Q Do you know approximately how much time  
4 you've billed in December?

5 A It's about the same. I -- I -- probably  
6 right around 18 to 20 hours.

7 Q Do you keep itemizations for your billings  
8 as to exactly what you were working on to generate  
9 the hours?

10 A I do, and that's reflected on these  
11 exhibits.

12 Q Okay. How much time have you spent since  
13 January in the last week or seven days preparing for  
14 this case or billing on this case?

15 A Can you repeat the question? I haven't  
16 submitted a bill for January.

17 Q Right. Approximately how -- and that was  
18 my question. How much time, approximately, that you  
19 spent since the beginning of January on this case or  
20 preparing for this deposition.

21 A I see. Probably in and around 10 to 15  
22 hours.

23 Q How much do you charge an hour for record  
24 review and deposition time?

25 A For record review, \$400 an hour. For an

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1 in-person meeting, \$500 an hour. For a scheduled  
2 teleconference, \$400 an hour. For a deposition, it  
3 would be \$600 an hour.

4 Q Can we jump ahead to Request No. 10. Did  
5 you comply with that request?

6 A No.

7 Q Do you keep any of your time sheets or  
8 invoices or records for all the consulting time that  
9 you've done for Ethicon?

10 A Only companies that I'm actively consulting  
11 with. So no.

12 Q So you no longer have any -- any of these  
13 documents that relate to your time consulting with  
14 Ethicon from 2007 to 2011?

15 A That's correct. I have one contract that I  
16 was able to locate, but I don't have any time sheets  
17 or invoices or any of those documents.

18 Q Do you have any of your e-mails that you  
19 have sent back and forth with Ethicon employees about  
20 consulting work?

21 A I don't have any of them. My personal  
22 e-mail changed. I used to be with hotmail. Now I'm  
23 with GMail, and I don't have access to hotmail  
24 anymore. That account has been closed.

25 Q Your hotmail account has been closed?

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1           **A**       Yeah. It's probably been closed for at  
2       least two to three years.

3           **Q**       Was there a point in time that you told  
4       Ethicon to quit e-mailing you at your University of  
5       Colorado e-mail and to e-mail you personally because  
6       you were concerned about the University of Colorado's  
7       policies on honorariums? Do you remember that?

8           **A**       I do.

9                   MR. SNELL: Form. Go ahead.

10          **A**       Yes.

11          **Q**       (By Mr. Kuntz) Okay. What is University  
12       of Colorado's policy on honorariums?

13          **A**       The university policy -- starting in 2010,  
14       they developed a conflict of interest policy.  
15       There's no policy before 2010.

16          **Q**       Have you provided information to them about  
17       your mesh consultation since 2010?

18                   MR. SNELL: Form, vague, "mesh  
19       consultation."

20          **Q**       (By Mr. Kuntz) I'm sorry. Mesh  
21       consultations.

22                   Have you informed the University of  
23       Colorado about all of the mesh companies you've been  
24       working with since 2010?

25                   MR. SNELL: Form and foundation, vague.

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1           **A**       Yes. I informed them of the work I did in  
2   2010 and, I believe, in 2011. There was no activity  
3   after those years, so there was nothing to inform  
4   them of.

5           **Q**       (By Mr. Kuntz) Okay. You don't believe  
6   you had a contract or were paid any money by mesh  
7   companies in 2011?

8           **A**       I was paid in 2010. I don't believe in two  
9   thousand -- maybe in 2011. I would have to look at  
10   the exact -- my tax return for those two years, but I  
11   can certainly say for 2012, '13, 2014 there was no  
12   activity.

13          **Q**       Okay. So you didn't receive any money for  
14   doing your expert report in the Carolyn Lewis case in  
15   2012?

16          **A**       Not directly from Ethicon.

17          **Q**       Okay. Were you paid by Butler Snow to  
18   perform the work in the Lewis case?

19          **A**       Yeah, by Butler Snow.

20          **Q**       Okay. And you don't have a duty to report  
21   to the University of Colorado outside litigation  
22   consulting you're doing for medical device  
23   manufacturers?

24          **A**       That's not part of the conflict of interest  
25   policy, no.

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1           **Q**     Is it part of the conflict of interest  
2     policy for the AUA? Do you know that?

3           **A**     To report medical-legal work?

4           **Q**     Yes.

5           **A**     Report it to whom?

6           **Q**     To the AUA or to the university.

7                   MR. SNELL: Objection, compound, form. Go  
8     ahead.

9           **Q**     (By Mr. Kuntz) Let me ask you this,  
10    Doctor: Have you ever reviewed the AUA conflict of  
11    interest policies?

12          **A**     Absolutely. I have to update them  
13    manually, and I'm actually listed as an expert  
14    witness on the AUA expert witness registry.

15          **Q**     If you were paid money by a mesh company,  
16    do you believe you have a duty to disclose that in  
17    any type of publication you publish?

18          **A**     If it pertains to that product, yes.

19          **Q**     What if it's a company that makes products  
20    about what the article is about?

21          **A**     You'd have to give me a more specific  
22    example.

23          **Q**     You're saying it has to relate to the exact  
24    product that the article is about? Is that your  
25    testimony?

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1           **A**     Again, that's too vague. I would need an  
2     example.

3           **Q**     Well, if you were receiving products from a  
4     company like AMS, who has female urology products --  
5     and maybe your consulting was only for male urology  
6     products and you were writing an article -- do you  
7     have a duty to disclose a relationship with AMS?

8                   MR. SNELL: Objection, form, vague as to  
9     "receiving products," and also foundation.

10          **A**     Are you saying receiving honorarium, Jeff?

11          **Q**     (By Mr. Kuntz) Yes.

12          **A**     Yes. So if you look at the update I wrote  
13     for the American Urologic Association, I disclosed on  
14     that document -- it's the first page -- my  
15     relationship with AMS and Ethicon even though I  
16     wasn't using any of AMS's products and I wasn't  
17     consulting with them on female urology, just on male  
18     urology.

19                   So I really tried to stick to the policy,  
20     and I update that annually on the Web site and in any  
21     publication that I'm involved in. I take that  
22     seriously.

23          **Q**     So -- and I think you answered my question.

24                   So if you were going to publish something  
25     and you had any type of relationship with AMS or

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1     Ethicon, you would make sure to disclose that in the  
2     publication?

3             MR. SNELL:  Objection, form --

4             **A**     We would have --

5                     (All speaking simultaneously, and reporter  
6                     requested clarification.)

7             MR. SNELL:  -- overbroad.

8             **A**     So what I responded to is:  You'd have to  
9     cite the specific publication you're referring to for  
10    me to give an appropriate answer.

11            **Q**     (By Mr. Kuntz)  Okay.  Well, you published  
12    in 2013 an article with Shah and Gilsdorf, Surgical  
13    Management of Lower Urinary Mesh Perforation.

14                     You know that article, correct?

15            **A**     Correct.

16            **Q**     International Urogynecology Journal?

17            **A**     That's correct.

18            **Q**     And you don't disclose any relationships  
19    with any mesh manufacturers in that article, correct?

20            **A**     Can we submit the article as an exhibit?

21            **Q**     We sure can.

22            **A**     Okay.

23                     MR. KUNTZ:  Sean, it's in the back.  It's  
24    in the folder Vaginal Sling Article.

25                     MR. KEITH:  Okay.

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1 MR. SNELL: Do you have a copy for me?

2 MR. KEITH: Yes.

3 MR. SNELL: Okay. Thank you.

4 MR. KEITH: I've got it. It's Exhibit 4,  
5 Jeff.

6 (Exhibit 4 was marked.)

7 MR. KEITH: It's published July 4, 2013.

8 MR. KUNTZ: It should be received April 8,  
9 2013. Yeah, published July 4, 2013. And that's  
10 Exhibit No. 4, I believe.

11 MR. KEITH: Exhibit 4, that's correct.  
12 Let's make sure we keep up with all the exhibits.  
13 That's the only thing -- because we've got a lot of  
14 papers on this desk.

15 (Discussion off the record.)

16 Q (By Mr. Kuntz) And, Doctor, in this  
17 article on the back page, it says "Conflict of  
18 Interest" and it says "None," correct?

19 A Correct.

20 Q And my question is: If you had a  
21 relationship with Ethicon in 2013, it would require  
22 you to disclose that in this article?

23 MR. SNELL: Objection, lacks foundation.

24 A Like I mentioned earlier, I wasn't  
25 consulting with Ethicon on any of their female

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1 urology products in 2013. So I was very -- I'm very  
2 comfortable with this disclosure, Jeff.

3 **Q** (By Mr. Kuntz) That's not my question.  
4 I'm sure you are.

5 Were you working with AMS in 2013 or  
6 receive any money from AMS in 2013?

7 **A** No.

8 **Q** Okay. If you did receive money from AMS,  
9 would you disclose that in the Conflict of Interest  
10 section of this article or should you have?

11 MR. SNELL: Compound, form.

12 **A** So I'd have to look at what International  
13 Urogynecology Journal requires. Each journal has  
14 their own standards.

15 The conflicts pertain to conflicts within  
16 that article. We're not obligated to list every  
17 single relationship we have in the article, only  
18 relationships that pertain to that article.

19 There's nothing in my relationships with  
20 AMS or Ethicon that related to this article.

21 **Q** (By Mr. Kuntz) Okay. I just thought you  
22 testified earlier that you take it very serious and  
23 you're very careful and you disclose everything, but  
24 now you're saying it depends on the article, it  
25 depends on the relationship, and it depends on the

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1 guidelines of the publication.

2 Is that what you're telling me now?

3 MR. SNELL: Objection, form, compound, also  
4 misstates prior testimony -- go ahead -- and asked  
5 and answered. Go ahead.

6 **A** Can you break the question down because  
7 it's a complicated one?

8 **Q** (By Mr. Kuntz) Let me ask you this: If  
9 you were receiving money from AMS in 2013, do you  
10 believe you had a duty to disclose that in this  
11 article?

12 MR. SNELL: Objection form, asked and  
13 answered.

14 **A** No, I don't. And, again, I said I don't  
15 have a relationship with them. I didn't have a  
16 relationship with them. I wasn't using their female  
17 urology products. I wasn't consulting on the female  
18 urology side; hence, there's no disclosure.

19 **Q** (By Mr. Kuntz) And I take it you don't  
20 feel a need to disclose in publications that you are  
21 consulting with Ethicon on litigation matters?

22 **A** If the article was about medical-legal  
23 matters, yes, I would disclose that, but if it was  
24 about a scientific article, a procedure or a disease,  
25 no.

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1           **Q**     In 2013, you write in this article that  
2     you, in the last six years -- so back in 2007, there  
3     was an alarming increase --

4                     (Reporter requested clarification.)

5           MR. KUNTZ: Yes. Sorry.

6           **Q**     (By Mr. Kuntz) In this article, you would  
7     agree that you write, "In the past six years, we have  
8     seen an increase in the overall number of  
9     transvaginal mesh complications. Cases referred to  
10    your center," correct?

11           MR. SNELL: What page are you on, Jeff, so  
12    we are all --

13           MR. KUNTZ: Page 3.

14           **A**     I believe I did make a comment in those  
15    regards. There's a few statements around that  
16    comment that explain that.

17           **Q**     (By Mr. Kuntz) Well, you thought the  
18    amount of complications that were coming in during  
19    that six-year period were an alarming increase,  
20    correct?

21           **A**     It was something that caused concern, yes.

22           **Q**     Why did it cause concern?

23           **A**     The ones involving the lower urinary tract  
24    -- you can see Figure 2 in 2012, for instance, there  
25    was almost 10. And so that is something that is a

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1 severe complication, and that was something that was  
2 concerning. I thought that physicians, the AUA,  
3 gynecologists would want to know that.

4 Q Can we go back to Exhibit A in the depo  
5 notice. Did you bring your copies of your 1099s?

6 MR. SNELL: I'm sure we objected to that,  
7 but we are not producing 1099s. Your experts had not  
8 produced any 1099s nor any billing records. So we  
9 will not be producing 1099s.

10 MR. KUNTZ: Even better.

11 Q (By Mr. Kuntz) Doctor, with your 1099s,  
12 you had some problems with Ethicon, didn't you, in  
13 the past as to how they were reporting those to the  
14 IRS?

15 A You'd have to be specific about what you  
16 mean by "problems."

17 Q Well, did you give notification to the IRS  
18 about Ethicon's billings to you on 1099s for  
19 consultation work?

20 A Ethicon was inconsistently issuing 1099s,  
21 and so I didn't want to create a red flag with the  
22 IRS. So I just asked them to please issue me a 1099  
23 so I know how much I made that year.

24 Q Okay. So -- well, were you issued 1099s in  
25 both your personal Social Security and your LLC that

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1 you bill through?

2 **A** No. That was the -- that was the concern,  
3 that it wasn't being sent to -- it wasn't being  
4 recorded under the right number.

5 **Q** Okay. So for several years income was  
6 being reported -- or recorded under two different  
7 numbers. Is that the problem?

8 **A** I wouldn't say several years. I would say  
9 for that year involved at least or maybe the previous  
10 year.

11 I know that there was a concern when I  
12 contacted them, and it had to be about a particular  
13 year, but I don't -- I don't know if it was several  
14 years.

15 **Q** Okay. So if we wanted to track down your  
16 total income for a year, would we have to look under  
17 both your Social Security number and your LLC tax ID  
18 number?

19 **A** I don't have an LLC. I have never had an  
20 LLC.

21 **Q** Have you had a company that you do your  
22 billings out of?

23 **A** Yes.

24 **Q** Okay. And what's the name of that?

25 **A** Flynn Consulting.

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1           **Q**     Okay. And how long has that been around?

2           **A**     Probably since 2007, 2008. I don't know  
3     the exact year.

4           **Q**     Is that who you still do your billings  
5     through now?

6           **A**     That's correct.

7           **Q**     You've been a paid consultant for Ethicon  
8     for over 10 years, correct?

9           **A**     Incorrect.

10          **Q**     Okay. How long have you been a consultant  
11     for Ethicon?

12          **A**     I mentioned earlier in the deposition from  
13     2004 to around 2011.

14          **Q**     And you only have one consulting agreement  
15     that you can find from -- I apologize. What year  
16     again?

17          **A**     It's 2011. It was a contract that I have  
18     here. I can submit that if you'd like.

19                 MR. KUNTZ: Yeah. Let's mark that as  
20     Exhibit No. 5.

21                 (Exhibit 5 was marked.)

22                 MR. SNELL: We've been going about an hour  
23     and a half. After this document, Jeff, can we take a  
24     break?

25                 MR. KUNTZ: We can take one now.

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1 (Recess from 2:52 p.m. to 3:13 p.m.)

2 Q (By Mr. Kuntz) Doctor, we're back on the  
3 record after a short break. I wanted to go back to  
4 something we were talking about before.

5 You said you have taught or proctored TVT  
6 Abbrevio training classes.

7 A Yeah. I was involved in a video that I did  
8 for Ethicon that was part of training for TVT  
9 Abbrevio.

10 Q Okay. Does that video discuss laser-cut  
11 mesh?

12 A No. That video is just a procedural video  
13 on how to do the procedure. Nothing more than that.

14 Q Okay. So never in that video does it  
15 discuss the Abbrevio being laser-cut mesh or any  
16 difference between the two meshes?

17 A Correct.

18 Q Have you ever taught an Abbrevio class to  
19 any surgeons that were about to use or using the TVT  
20 Abbrevio product?

21 A I work at a teaching institution. I have  
22 fellows and residents, medical students I teach every  
23 day. And yes, I mention to them laser cut,  
24 mechanically cut. It's a conversation I've had with  
25 people that work around me.

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1           **Q**     Okay. And that wasn't exactly my question  
2     about the "people that work around me."

3                   Have you ever taught a class for Ethicon  
4     about the TVT Abbrevio?

5           **A**     I'm uncertain. I don't know when I -- I  
6     mentioned I think the last event I did for Ethicon  
7     was in and around 2010, and I don't remember the  
8     exact content of those events, if it was TVT Abbrevio  
9     or TVT Exact.

10          **Q**     Do you ever remember discussing or telling  
11     surgeons at an Ethicon event about the differences of  
12     laser-cut mesh and mechanical-cut mesh?

13          **A**     Not in a formal session. When we would  
14     have cadaver labs, you know, those conversations  
15     would come up when we were instructing in small group  
16     sessions.

17          **Q**     And what would you tell surgeons about  
18     laser-cut mesh?

19          **A**     That there's some subtle differences in the  
20     tensioning.

21          **Q**     What kind of subtle differences in the  
22     tensioning are there between laser-cut mesh and  
23     mechanical-cut mesh?

24          **A**     Oh, for one, that the laser-cut mesh was  
25     easier to deploy. So it was less likely -- you know,

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1 I should say it was easier just to insert and to get  
2 it to lie correctly. I would make that comment.

3 And then more specifically in terms of  
4 tensioning, I would say that generally we tension it  
5 slightly looser than we would do on mechanically-cut  
6 mesh.

7 Q Have you ever reviewed any documents from  
8 Ethicon in preparation to form your opinions in this  
9 case that talk about laser-cut mesh and the  
10 deployment of it?

11 A I have, and I have documents in the folder  
12 I had in front of me in regards to some testing that  
13 was done.

14 Q Okay. And I understand there's documents  
15 related to testing, and we're going to get into that,  
16 but do you specifically recall seeing any documents  
17 related to the deployment of the laser-cut mesh?

18 A I've read some comments, some memos --  
19 intraoffice memos amongst employees, but I don't --  
20 nothing was sent to me directly or -- you know, I  
21 didn't receive a letter. It didn't appear in a  
22 PowerPoint presentation.

23 Q Do you recall reviewing any specific  
24 documents in this case while forming your opinions  
25 about tensioning in laser-cut from Ethicon employees?

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1           **A**     Yes.

2           **Q**     And what do you recall about those  
3 documents, or what documents did you review?

4           **A**     I can't remember the specific documents  
5 without having them in front of me, but just in  
6 general, that people were at least opening up the  
7 discussion on what key opinion leaders and others  
8 thought about how to tension it. Should it be  
9 tensioned the same or differently.

10          **Q**     Do you recall reviewing any documents that  
11 physicians -- or strike that.

12                   Do you recall reviewing any documents in  
13 forming your opinion in this case about Ethicon  
14 employees having concerns about tensioning with  
15 laser-cut mesh?

16          **A**     I think that there was some awareness. I  
17 guess you could use the word "concern." There was  
18 discussion, like I mentioned, that it's something  
19 that people who instruct on the procedure were  
20 wondering what they should be telling their students.

21          **Q**     Is there any -- you had talked about easier  
22 to deploy and tensioning -- I think you said looser  
23 with the laser-cut mesh are things you taught at  
24 cadaver labs, correct?

25          **A**     Those were comments that I would make to

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1 people who would ask me advice about it. I can't say  
2 for sure it occurred at a cadaver lab. It could have  
3 occurred at other Ethicon events or at scientific  
4 meetings or just, you know, amongst -- conversation  
5 with colleagues in other specialties at the hospitals  
6 that I work at.

7 Q What do you tell your students at  
8 University of Colorado about laser-cut mesh versus  
9 mechanical-cut mesh?

10 A Well, at this point, it's not a  
11 conversation we really have because all we've been  
12 using is laser-cut mesh really since it became  
13 available.

14 So it's more of a historic conversation.  
15 That probably would be beyond what a student would be  
16 interested in, but it was conversations that I had,  
17 you know, when there was a transition period.

18 So during those years, say, from '7 to like  
19 '10 or '11, it would be a conversation, but once we  
20 had a group of residents who only had experience with  
21 the laser-cut, that's all they knew. They really  
22 didn't need to understand tensioning mechanically-cut  
23 because it was something that I wasn't using in my  
24 practice; hence, they wouldn't be using.

25 Q Is the TVT Exact laser-cut mesh?

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1           **A**     It is, yes.

2           **Q**     Is -- do you believe laser-cut mesh is  
3     better than mechanical-cut mesh?

4           **A**     I would say it's different. I prefer it,  
5     but I don't think there's any scientific studies to  
6     say it's superior.

7           **Q**     Do you -- have you read any deposition of  
8     Ethicon employees that believe that the laser-cut  
9     mesh is superior to the mechanical-cut mesh?

10           MR. SNELL: Foundation objection. Go  
11     ahead.

12           **Q**     (By Mr. Kuntz) I guess you haven't read  
13     any internal depositions from any Ethicon employees?

14           **A**     No. I've just seen bits and pieces from  
15     depositions. Some of them in the form of exhibits  
16     that were put in front of me in other depositions  
17     that I've given, and then some of the in-house  
18     documents that I have in front of me, they -- but no,  
19     I don't have a lot of that information. I wasn't  
20     privy of a lot of that information.

21           **Q**     Did you ever, in forming your opinions,  
22     think, "Hey, maybe I want to read what the internal  
23     Ethicon employees, scientists, and medical directors  
24     were saying about the issues in this case"?

25           MR. SNELL: Objection, form, compound.

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1           **A**     No. I don't think that's really my role in  
2     this case. I'm not a materials science expert, and I  
3     think there's other people that are experts for  
4     Ethicon that can probably speak to it better than me.

5           **Q**     (By Mr. Kuntz) Speak to what better than  
6     you?

7           **A**     Speak to the biomechanical data, if there's  
8     any differences. I'm aware of differences that I see  
9     grossly with my naked eye when I have the material in  
10    front of me, you know, how the edges are smoother on  
11    the mechanically-cut, how the mesh is -- appears to  
12    be brighter or bluer.

13           You know, those are things that I see, you  
14    know, in my practice and when I'm implanting a mesh.

15           **Q**     So you believe other people are suited to  
16    talk about the scientific or differences between  
17    laser-cut mesh and mechanical-cut mesh as opposed to  
18    you?

19           MR. SNELL: Objection. It misstates.

20           **A**     I'm stating I'm prepared to answer  
21    questions as a physician and a clinician with respect  
22    to laser-cut and mechanically-cut, but I'm not an  
23    employee of Ethicon. I didn't develop the mesh.

24           I feel there's people better in the company  
25    to explain those differences than I am, yes. I'm not

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1 a practicing engineer. I'm not the inventor of the  
2 mesh. I didn't develop the mesh. I didn't bring it  
3 to market. So I think those questions are better for  
4 Ethicon than me.

5 **Q** (By Mr. Kuntz) Okay. Do you believe that  
6 the laser-cut mesh is stiffer than the mechanical-cut  
7 mesh?

8 **A** I think there's probably as much as 4 to 5  
9 percent difference between the two meshes. Like I  
10 mentioned earlier, there's some subtle differences.  
11 And so if that mesh is less elastic and doesn't have  
12 the same amount of elongation, then you're going to  
13 want to tension it looser. That's how I feel, and  
14 that's how I practice.

15 **Q** So you do agree that the laser-cut mesh is  
16 stiffer than the mechanical-cut mesh?

17 **MR. SNELL:** Objection. It misstates.

18 **A** I'm not going to agree to that, no.

19 **Q** (By Mr. Kuntz) Okay. So you -- okay. So  
20 you -- you disagree that the laser-cut mesh is  
21 stiffer than the mechanical-cut mesh? That's your  
22 testimony?

23 **A** My testimony is, there's not a clinically  
24 significant difference, you know, one that reaches  
25 significance. It's less than 5 percent. They're

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1 subtle differences, and that's going to be my  
2 testimony.

3 Q Okay. So your testimony under oath is that  
4 there's no clinical difference between the laser-cut  
5 and mechanical-cut mesh, correct?

6 A Incorrect.

7 Q Well, I thought that's what -- okay. Let's  
8 try this again because you keep changing around on  
9 me, Doctor. It's a really simple question, a  
10 two-parter.

11 Do you believe the laser-cut mesh is  
12 stiffer than the mechanical-cut mesh? Yes or no?

13 MR. SNELL: Objection, asked and answered.

14 A Like I said earlier, no.

15 Q (By Mr. Kuntz) Do you believe that there  
16 is clinical complications that are different with the  
17 laser-cut mesh compared to the mechanical-cut mesh?

18 A No.

19 Q Do you believe that -- strike that.

20 Do you believe that the different -- strike  
21 that.

22 Do you believe there's no clinical  
23 significance between the laser-cut mesh and the  
24 mechanical-cut mesh?

25 MR. SNELL: Objection, asked and answered.

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1           **A**       Correct. I don't believe there's any  
2       clinical significant difference between laser-cut and  
3       mechanical-cut in my own practice or what's reported  
4       in the literature or from conversation with  
5       colleagues.

6           **Q**       (By Mr. Kuntz) What literature are you  
7       talking about?

8           **A**       There's just the volumes of records here I  
9       have in front of me, my own personal review of the  
10      medical literature.

11                I personally have never read an article in  
12      the medical literature that shows any clinical  
13      differences between laser-cut and mechanically-cut.

14           **Q**       Doctor, do you know if a study has ever  
15      been performed to look at the differences between --  
16      strike that.

17                Doctor, do you know if there's ever been a  
18      clinical study performed to look at the differences  
19      between laser-cut mesh and mechanical-cut mesh?

20           **A**       I'm not aware of that study, not a clinical  
21      study.

22           **Q**       Have you ever seen any internal Ethicon  
23      documents discussing the need for a clinical study to  
24      determine the differences between laser-cut mesh and  
25      mechanical-cut mesh?

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1           **A**       No.

2           **Q**       Have you ever seen any documents from  
3       Ethicon discussing clinical complications that arose  
4       because of laser-cut mesh versus mechanical-cut mesh?

5           **A**       I have not.

6           **Q**       None of those documents, as you sit here  
7       today, have been provided, if they exist, to you by  
8       Ethicon's counsel? You haven't reviewed them, have  
9       you?

10                   MR. SNELL: Objection, foundation.

11           **A**       I have the documents that I have brought on  
12       laser-cut and mechanically-cut. We can go through  
13       those, but I don't have anything that calls for a  
14       trial or, you know, raises concern beyond the issues  
15       I mentioned earlier.

16                   The issues we mentioned earlier are subtle  
17       differences with tensioning and --

18           **Q**       (By Mr. Kuntz) Okay.

19           **A**       -- you know, those conversations.

20           **Q**       And so you prepared -- you've prepared for  
21       six months for this deposition. You've met with  
22       lawyers -- two lawyers five times and had  
23       approximately 20 phone calls, and you've never seen  
24       any Ethicon internal documents to discuss the concern  
25       about clinical complications of laser-cut mesh?

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1 MR. SNELL: Objection, vague. It  
2 misstates.

3 A That's correct. I have not seen documents  
4 from Ethicon that discuss complications from  
5 laser-cut versus mechanically-cut.

6 Q (By Mr. Kuntz) Do you agree in general  
7 that it's better to have a less stiff mesh in an SUI  
8 product?

9 A That's overly vague. I can't agree one way  
10 or the other. There's an optimal amount of  
11 stiffness. There's an optimal amount of tension.  
12 And you don't want it too loose; you don't want it  
13 too tight. And it's something that we deal with  
14 every day in our practice.

15 Q And I'm not talking about tensioning,  
16 Doctor. I'm asking you a very simple question.  
17 Do you believe it's better to have a less  
18 stiff mesh as opposed to a rigid mesh?

19 MR. SNELL: Objection, form, asked and  
20 answered.

21 A I would say no. My answer is no.

22 Q (By Mr. Kuntz) Okay. And so you would  
23 disagree with any person who made a statement that  
24 it's better to have a less stiff mesh for an SUI  
25 product?

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1 MR. SNELL: Objection, lacks foundation,  
2 vague.

3 A It would depend on the context of the  
4 conversation. I think that -- tensioning and  
5 stiffness, those two things go hand in hand, and  
6 there's an optimal amount of tension, and that  
7 optimal amount of tension comes from characteristics  
8 of the mesh.

9 If the mesh is too elastic, it's not going  
10 to work. If it's too stiff, potentially it can cause  
11 complications. So you have to find the right  
12 balance.

13 Q (By Mr. Kuntz) So would you agree -- you  
14 keep talking about tensioning.

15 Would you agree that the forces applied to  
16 a mesh during implantation and tensioning can relate  
17 to the stiffness?

18 MR. SNELL: Objection, form, overbroad as  
19 application.

20 A I would say that tensioning and the mesh  
21 characteristics -- in terms of stiffness or  
22 elongation, elasticity, those things go hand in hand.  
23 They're very closely associated with one another.

24 Q (By Mr. Kuntz) Do you agree that a stiffer  
25 mesh can cause more erosion?

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1           **A**     Can you define the word "erosion"?

2           **Q**     What's your definition of "erosion,"  
3     Doctor?

4           **A**     I don't use the word "erosion" anymore. I  
5     try to follow the ICS and IUGA classification and  
6     terminology with respect to mesh implants.

7           **Q**     Do you understand --

8                   (Reporter requested clarification.)

9           **Q**     (By Mr. Kuntz) Do you understand Ethicon  
10    still uses the word "erosion," Doctor?

11          **A**     I think everyone still uses the word, but  
12    it's a word that we're trying to avoid using.

13          **Q**     Okay. Have you told Ethicon that they need  
14    to take that out of their IFU or internal documents  
15    that go to doctors, the word "erosion"?

16          **A**     I have not.

17          **Q**     Okay. Would you agree that a stiffer mesh  
18    can cause more exposures?

19                   MR. SNELL: Objection, form, vague.

20          **A**     I -- I think if it was extreme, yes.

21          **Q**     (By Mr. Kuntz) Okay. Do you have any  
22    idea, as you sit here today, why Ethicon switched  
23    from mechanical-cut mesh to laser-cut mesh?

24          **A**     My general understanding was that that's  
25    what some of the competing products had done, and

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1 they were receiving positive feedback from  
2 physicians, and so it was something that physicians  
3 wanted.

4 Q And why did physicians want laser-cut mesh  
5 over mechanical-cut mesh?

6 A I think there's this general understanding  
7 that if the edges look smoother and they're  
8 nontanged, then there would be less exposure, less  
9 pain, less perforation if the edges were smoother.  
10 So that's why physicians wanted that.

11 Q Do you have any idea, as you sit here  
12 today, about any other reasons why Ethicon switched  
13 from mechanical-cut mesh to laser-cut mesh?

14 A No. I don't have any other reasons beyond  
15 trying to meet the needs of their physicians.

16 Q Tell me exactly how the tensioning of the  
17 mesh for laser-cut differs from that with  
18 mechanically-cut mesh.

19 A So what I mentioned earlier is the -- my --  
20 at least -- own personal initial impressions were,  
21 that I was going to tension the mesh looser with  
22 laser-cut than with mechanically-cut since there was  
23 less deformity and less potential for elongation,  
24 that the mesh would be less likely to loosen over  
25 time.

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1           **Q**     Doctor, you believe that dyspareunia  
2     increases in the use with laser-cut mesh versus  
3     mechanical-cut mesh, don't you?

4                   MR. SNELL:  Objection.  It misstates.  It  
5     lacks foundation.

6           **A**     I would not agree to that statement.

7           **Q**     (By Mr. Kuntz)  Okay.  You've never made  
8     that statement in the past to Ethicon?

9           **A**     I don't believe so, no.

10          **Q**     If you've made that statement to Ethicon in  
11     the past, then it was wrong, correct?

12          **A**     I don't believe I ever made that statement.  
13     That --

14          **Q**     Do you remember having discussions with  
15     Ethicon about laser-cut versus mechanical-cut mesh?

16                   MR. SNELL:  Form, vague as to application.

17          **Q**     (By Mr. Kuntz)  Have you had meetings with  
18     engineers and medical directors?

19                   MR. SNELL:  Same objection.  Foundation  
20     now.  Also form as to application.

21          **A**     No, I don't remember having any  
22     conversations that I had personal concerns over the  
23     laser-cut mesh.

24          **Q**     (By Mr. Kuntz)  Okay.  Especially as it  
25     relates to dyspareunia, correct?  You don't remember

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1 that conversation?

2 MR. SNELL: Same objections, asked and  
3 answered.

4 A I don't believe the conversation -- ever  
5 had it. It's not that I don't remember it. I didn't  
6 have that conversation with Ethicon.

7 Q (By Mr. Kuntz) Even better. Thanks.

8 Have you ever talked to any physicians that  
9 has concerns with laser-cut mesh?

10 A What I mentioned earlier is that physicians  
11 would ask me how I would tension laser-cut mesh  
12 versus mechanically-cut.

13 It was a question that I had received in  
14 various programs or in my own practice. And what I  
15 told them is that I was generally going to tension it  
16 looser.

17 The reason I felt that way is, I had  
18 experience with the Boston Scientific Advantage Fit.  
19 I had experience with AMS Sparc.

20 And so, you know, I was just trying to find  
21 the right balance. I feel there were subtle  
22 differences in tensioning, and I -- that was just my  
23 own personal feelings about that, and I would give  
24 people my own anecdotal experience in that. It was  
25 nothing scientific. It was just from my own clinical

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1 experience.

2 Q And that wasn't my question, but my  
3 question was: Have you ever had any physicians tell  
4 you that they were having problems with the laser-cut  
5 mesh?

6 A No.

7 Q I want to go back to -- I think we marked  
8 as Exhibit 4 or 5 your consulting agreement with  
9 Ethicon.

10 A Okay.

11 Q And that -- and I apologize. That's your  
12 2011 contract?

13 A That's a 2011 contract.

14 Q Okay. Did you have a contract with them in  
15 2004 as well?

16 A I believe I had contracts with them during  
17 the period of time I was consulting. Each year the  
18 contract came for renewal.

19 Q So you had a contract every year with them,  
20 a consulting agreement from 2004 to 2011?

21 A I would say for the most part it was a  
22 continuous relationship. There may have been some  
23 short gaps, but yes.

24 Q Okay. Do you have any idea, as you sit  
25 here today, how much those contract amounts called

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1 for for each particular year?

2 MR. SNELL: Objection, form, vague, "called  
3 for."

4 A I could read from the 2011 one. I can't  
5 remember before '11, but I don't think the amounts  
6 changed a whole lot over the years.

7 So what's listed on the 2011 contract is  
8 probably fairly representative of that time period.

9 Q (By Mr. Kuntz) And the 2011 contract has a  
10 maximum amount of \$50,000. Do you see that?

11 A I thought it was 75,000, but I have to find  
12 it in this contract. So I'm flipping through the  
13 contract right now.

14 (Pause.)

15 A There's the daily per diem rates. There's  
16 an hourly rate. There's probably a maximum in here  
17 somewhere. I'm just not seeing it immediate.  
18 There's numbers on travel expenses.

19 Q Do you know how much you were paid by  
20 Ethicon in 2011?

21 A I don't know the amount.

22 Q Do you know the amount you were paid by  
23 Ethicon in 2004?

24 A No.

25 Q Do you know the amount that you were paid

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1 by Ethicon in 2005?

2 **A** No.

3 **Q** Have you ever been paid over \$100,000 in  
4 one year by Ethicon?

5 **A** Never.

6 **Q** Ever?

7 **A** Never ever.

8 **Q** If there were any documents -- internal  
9 documents from Ethicon that state that, do you  
10 believe those would be wrong?

11 **A** That would be correct.

12 **Q** Okay. Do you think reports to the  
13 government and Medicare payment systems about amounts  
14 paid for each year would be wrong?

15 **A** That's a question for Ethicon. I don't  
16 know how they did their reporting, but I know I never  
17 made more than \$100,000 in a single year.

18 **Q** Okay. Have you ever made over \$50,000 in a  
19 single year from Ethicon?

20 **A** I don't recall.

21 **Q** Do you know how much you made from Ethicon  
22 in 2005?

23 **A** No.

24 **Q** 2007?

25 **A** No.

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1           **Q**     2008?

2           **A**     No.

3           **Q**     2009?

4           **A**     Yes.

5           **Q**     Why do you know 2009?

6           **A**     The University of Colorado, when they  
7 started their conflict of interest policy in 2009 and  
8 2010, they asked us to report that. So I remember  
9 preparing that for the years 2009 and 2010.

10          **Q**     And what did you report to them in 2009?

11          **A**     I believe it was around \$1,000.

12          **Q**     Were you required by University of Colorado  
13 in 2009 to report to them the total amount you had  
14 been paid by Ethicon for consulting work?

15          **A**     No. The policy began in 2010, but they had  
16 a period of time where they encouraged people to  
17 offer previous relationships as well.

18          **Q**     Okay. And so in 2009, you reported to the  
19 University of Colorado that you had made \$1,000 from  
20 Ethicon?

21          **A**     I believe that's what I told them.

22          **Q**     Do you have any idea what you made in 2010?

23          **A**     It was somewhere around 21- or \$22,000.

24          **Q**     And that's what you reported to the  
25 University of Colorado?

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1           **A**       That's correct.

2           **Q**       What about 2011?

3           **A**       I don't believe I reported anything. I  
4 don't believe I made anything in 2011 and on, from  
5 those years forward.

6           **Q**       Okay. So it's your belief you weren't paid  
7 anything from Ethicon in 2011?

8           **A**       I have to go back and look at the exact  
9 record, but I was paid for doing the TVT Abbrevio  
10 video, and that was the last consulting project, the  
11 video that I did with them. So it was either 2010 or  
12 2011.

13          **Q**       Okay. This is a really dumb question.  
14 There's not another Brian Flynn at the University of  
15 Colorado, is there?

16          **A**       There is, but I'm the only Brian Flynn  
17 who's a physician there.

18          **Q**       Okay. How much did you charge Ethicon for  
19 all your work on the Carolyn Lewis case?

20          **A**       I'd have to go back and look at the  
21 invoices, but it was a similar amount of work to this  
22 case. So my best estimate would be somewhere between  
23 15- and \$20,000.

24          **Q**       Okay. Have you ever reviewed any Ethicon  
25 internal documents that they call you one of their

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1 key surgeons?

2 **A** I believe I saw that in an exhibit from a  
3 previous deposition.

4 **Q** Have you ever reviewed any documents that  
5 Ethicon calls you one of their go-to people?

6 **A** I'm not familiar with that document.

7 **Q** Okay. How many events do you think you've  
8 attended since 2004 up until -- your time consulting  
9 for Ethicon ending in 2011 do you think you've  
10 attended on behalf of Ethicon?

11 MR. SNELL: Objection, form and foundation,  
12 vague also.

13 **A** So can you define the word "event"?

14 **Q** (By Mr. Kuntz) Well, let's start -- how  
15 many dinners have you been to with Ethicon over that  
16 seven-year period?

17 **A** In terms of me being the speaker of the  
18 dinner program or an attendee?

19 **Q** The attendee.

20 **A** As an attendee --

21 **Q** Yes.

22 **A** -- probably 15 to 20.

23 **Q** Okay. How many -- if you just had to  
24 guess, how many different states have you been to on  
25 behalf of Ethicon for dinners or preceptorships or

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1 speaker engagements?

2 **A** How many different states?

3 **Q** Yes.

4 **A** Yes. Okay. Well, I was a preceptor in the  
5 western United States. That's where most of my  
6 activity was. So Colorado, Arizona, Nevada,  
7 California. And then if there was a summit, I  
8 attended one in Florida and one in Baltimore,  
9 Maryland. And I've been to the home office in New  
10 Jersey.

11 **Q** How many times have you been there?

12 **A** I've been to Somerville, New Jersey, to the  
13 J&J probably once or twice. And we were at events,  
14 you know, on the campus in neighboring conference  
15 centers. I wasn't in the lab. I wasn't in the  
16 actual, you know, buildings or -- it was a summit  
17 that I attended in New Jersey. It was in New  
18 Brunswick, which is just right next-door.

19 And then there was a hospital that they  
20 would do activity at with Dr. Labib Riachi that I  
21 attended. I believe that's maybe in Hackensack.

22 **Q** How many summits have you been to for  
23 Ethicon?

24 **A** Three or four.

25 **Q** So 15 to 20 dinners, three to four summits

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1     you think?

2                   MR. SNELL:  Objection, asked and answered.

3           **A**     Dinners that I was an attendee or lunch?

4     That might -- some of those might have been -- 15 to

5     20 lunch or dinners and then the three to four

6     summits.

7           **Q**     (By Mr. Kuntz)  And were those all in New

8     Jersey?

9           **A**     No.  No.  The dinners were usually at

10    meetings that I would have been attending anyway, and

11    the summits were at various locations.

12          **Q**     How many different advisory boards have you

13    been on for Ethicon?

14          **A**     Just one.

15          **Q**     Do you remember what year that was?

16          **A**     It was 2010.  Maybe 2009.  One of those

17    years.  Either '9 or '10.

18          **Q**     How many speaking engagements have you been

19    to for Ethicon?

20                   MR. SNELL:  Form, vague, "been to."

21          **A**     As the speaker?

22          **Q**     (By Mr. Kuntz)  Yeah.

23          **A**     Probably 5 to 10.

24          **Q**     Have you ever traveled overseas for

25    Ethicon?

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1           **A**     No.

2           **Q**     Did you keep any of your PowerPoints where  
3     you were the speaker?

4           **A**     Yes.

5           **Q**     Did you bring those with you today?

6           **A**     I have.

7           **Q**     Okay. Do you agree that Ethicon has to  
8     have final approval over your PowerPoints before you  
9     speak?

10           MR. SNELL: Objection. Form as to scope.

11           **A**     No, I don't agree with that.

12           **Q**     (By Mr. Kuntz) Do you agree that you've  
13     given Ethicon your permission to use your name and  
14     bio to promote its products?

15           MR. SNELL: Objection, foundation.

16           **A**     I disagree with that.

17           **Q**     (By Mr. Kuntz) You disagree with that  
18     statement?

19           **A**     I disagree that I gave them permission to  
20     use my name to promote their products.

21           **Q**     Okay. How many company sales training  
22     presentations have you attended?

23           **A**     As an attendee?

24           **Q**     Yeah.

25           MR. SNELL: I'm going to object as vague as

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1 to which company you're talking about.

2 MR. KUNTZ: Ethicon.

3 MR. SNELL: Okay. Then I'll withdraw that  
4 objection. Go ahead.

5 A Three to four.

6 Q (By Mr. Kuntz) How many product review  
7 meetings with Ethicon have you attended?

8 A Well, that was the function of the advisory  
9 board. So those two things are one and the same. I  
10 believe we met annually, and we would have occasional  
11 conference calls maybe once or twice a year.

12 Q How many cadaver courses or preceptorships  
13 have you ran for Ethicon?

14 A I never ran any. I was never the director  
15 of any of those.

16 Q How many did you teach at?

17 A I would say 10 to 15.

18 Q Did I ask you how many product advisory  
19 boards you had been a part of?

20 A Just one for Ethicon.

21 Q Have you been involved with any product  
22 research teams with Ethicon?

23 A I'm not certain what you mean by "research  
24 team."

25 Q Have you ever heard the term "product

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1 evaluation teams"?

2 **A** No.

3 **Q** Have you ever performed any of these  
4 things, advisory boards, training presentations,  
5 dinners, with AMS?

6 **A** Not for female urology.

7 **Q** For what, male urology products?

8 **A** Artificial urinary sphincter and male  
9 sling.

10 **Q** Okay. Have you ever attended any events  
11 for Boston Scientific as it relates to female urology  
12 products?

13 **A** I've been to a dinner, but I've never been  
14 to any cadaver labs or anything as it relates to  
15 professional education.

16 **Q** How many events do you think you've been to  
17 on the male urology products for AMS?

18 **A** As an attendee or as a speaker?

19 **Q** Either/or. Total number of events that  
20 you've attended or as a speaker. I mean combined.  
21 Let's just take them one at a time. As an attendee.

22 **A** As an attendee, three or four.

23 **Q** What about as a speaker?

24 **A** 5 to 10.

25 **Q** What about for Bard? Have you attended any

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1 events for Bard female urology products?

2 **A** No.

3 **Q** Do you do any consulting work with any drug  
4 companies?

5 **A** Not at this point.

6 **Q** What have you done in the past?

7 **A** From 2004 to 2008 or '9, I did some work  
8 for Pfizer and for Astellas.

9 **Q** What products?

10 **A** Drugs for overactive bladder. Pfizer's  
11 drug was Toviaz. Astellas's drug was VESicare.  
12 Currently I am involved in a clinical trial for  
13 Allergan, looking at Botox.

14 **Q** Do you agree with this statement: A  
15 financial conflict of interest exists when an  
16 individual is in or may reasonably be perceived to be  
17 in a position to gain or suffer financial loss as a  
18 result of an action?

19 **MR. SNELL:** Objection, form, vague, lacks  
20 foundation.

21 **A** Yeah, I can't agree with that statement.  
22 It's too vague.

23 **Q** (By Mr. Kuntz) So you've never heard that  
24 statement before?

25 **A** I've heard that statement commonly,

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1 actually, and it's a statement that I think is very  
2 poorly written.

3 Q Do you know where that statement comes  
4 from?

5 A It comes from a number of professional  
6 societies and medical schools.

7 Q Why do you think it's poorly written?

8 A It's not clear. I think that there's so  
9 many different scenarios that exist that you would  
10 really need to have some well-defined case studies  
11 describing each scenario to see how people would view  
12 that.

13 Q Are you a member of the American Board of  
14 Urology?

15 A I am.

16 Q Have you reviewed their conflict of  
17 interest statements?

18 A I have.

19 Q Okay. Do you agree that they say  
20 relationships between industry and opinion leaders  
21 should be disclosed?

22 MR. SNELL: Objection, foundation. Form as  
23 to -- it sounds like it's incomplete. The document,  
24 I would assume, speaks for itself, too.

25 A Yeah, I think I said earlier in the

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1 deposition each event needs to be looked at  
2 individually, whether it's a scientific article, it's  
3 a meeting, it's a presentation.

4 I probably fill out a conflict of interest  
5 statement almost weekly. It's that common from that  
6 many different sources. So it's something that I'm  
7 well aware of, and they're all written and looked at  
8 differently. So that's my statement.

9 Q (By Mr. Kuntz) Do you tell your patients  
10 when you're going to implant an Ethicon product in  
11 them, that you consulted with them for seven years in  
12 the past?

13 A I tell them I have a long-standing  
14 relationship with Ethicon. I don't use the word  
15 "consult." Most patients don't understand what that  
16 means.

17 Q Do you tell them that you've been paid  
18 money by Ethicon?

19 A I tell them that I work with them and that  
20 I stand behind their products and I have a lot of  
21 confidence in their products.

22 Q Do you have a duty to go back and  
23 supplement amounts made in years for University of  
24 Colorado the numbers you submitted are incorrect?

25 MR. SNELL: Objection, improper

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1 hypothetically, calls for a legal conclusion.

2 **A** I think we've been through that.

3 Everything before 2010 I have no responsibility.

4 Around 2010 into '11 is when the policy came into  
5 place. I'm very comfortable with what I've disclosed  
6 to them.

7 **Q** (By Mr. Kuntz) And your 1099s would tell  
8 us really how much you made from Ethicon in those  
9 years, wouldn't it, Doctor?

10 That's the only documents we know what you  
11 report to the government and what Ethicon reports to  
12 the government as to what you made in those years  
13 from Ethicon, correct?

14 **A** Incorrect.

15 **Q** Okay. How else do you know?

16 **A** I don't really know. I mentioned earlier  
17 that the 1099s were being issued inconsistently, and  
18 that was something I tried to make Ethicon aware of  
19 because many of us didn't know exactly what we were  
20 making.

21 **Q** Well, somebody knows exactly how much you  
22 were making, correct?

23 MR. SNELL: Objection, foundation.

24 **Q** (By Mr. Kuntz) You pay taxes on it with a  
25 1099. You have to tell the government what you made

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1 from Ethicon, correct?

2 **A** Incorrect.

3 **Q** So you don't have to report to the  
4 government your total income from Ethicon in a given  
5 year?

6 MR. SNELL: Objection, form, calls for a  
7 legal conclusion.

8 **A** I have an obligation to tell the government  
9 what I feel I made, and that's hard when you don't  
10 receive a 1099. That's what I was trying to voice to  
11 Ethicon.

12 **Q** (By Mr. Kuntz) Did you ultimately receive  
13 1099s from Ethicon that were appropriate and  
14 accurate?

15 **A** Not for all of those years involved.

16 **Q** Did you have any role in the marketing of  
17 TVT Abbrevio?

18 **A** I had a role in making the video. That was  
19 my role in the TVT Abbrevio. That was my role.

20 **Q** So all you did with TVT Abbrevio was make  
21 the video?

22 **A** Well, I helped with the narration on the  
23 video, you know, describing key procedural steps.  
24 That was my position on TVT Abbrevio. That was my  
25 role in the project.

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1           **Q**     Do you know how much Ethicon makes on each  
2     Abbrevio it sells?

3           **A**     I know the list price, but I don't know  
4     what their margin is.

5           **Q**     You've never reviewed any documents from  
6     Ethicon that discuss their profit margins on the TVT  
7     Abbrevio?

8           **A**     Never.

9           **Q**     How much money do you make on each Abbrevio  
10    that you put in?

11                   MR. SNELL:  Objection, foundation.  Go  
12    ahead.

13           **A**     That would depend on the insurer.

14           **Q**     (By Mr. Kuntz)  Okay.  Well, how about for  
15    -- well, what private insurance do you take?

16           **A**     We take United.  We take Rocky Mountain  
17    Health Plan.  We see some Kaiser, Aetna, Cigna.

18           **Q**     Okay.  Do you have any idea, on any of  
19    those, what prices you charge or what you make on  
20    each Abbrevio you put in?

21                   MR. SNELL:  Form and foundation as to "you  
22    charge."

23           **A**     University of Physicians, Incorporated,  
24    submits the bill, and the bill -- typically just for  
25    the surgical portion of the procedural, the surgeon's

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1 fee is around \$3,000. Typically we receive 6- to  
2 \$700 for the procedure.

3 Q (By Mr. Kuntz) You still believe the Burch  
4 procedure is still within the standard of care,  
5 correct?

6 A Correct.

7 Q You believe pubovaginal slings are still  
8 within the standard of care?

9 A Yes.

10 Q And do you still teach Burch and  
11 pubovaginal sling at the University of Colorado?

12 A Pubovaginal sling. Burch, I do such a  
13 limited number of them that it's difficult for me to  
14 teach that.

15 Q Do they still teach the Burch procedure at  
16 Duke University?

17 A I believe so.

18 Q Do they still teach pubovaginal slings at  
19 Duke University?

20 A I believe so.

21 Q And you'd agree with me that there's many  
22 medical schools and universities throughout the  
23 United States that still teach the Burch and  
24 pubovaginal sling?

25 MR. SNELL: Foundation objection. Go

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1 ahead.

2           **A**     You'd have to tell me which years. I think  
3 in recent years people are starting to relearn, if  
4 you will, or teach those procedures again.

5           There was a big gap of probably about 10 to  
6 15 years where residents and fellows weren't learning  
7 those procedures because they weren't really being  
8 taught or they were being done in such few numbers  
9 that it was hard for people to feel comfortable doing  
10 those procedures after graduation.

11           **Q**     (By Mr. Kuntz) But today, as we sit here  
12 now, there's numerous medical schools that are  
13 teaching the Burch and pubovaginal sling, correct?

14           MR. SNELL: Objection, asked -- sorry.  
15 Object to form, asked and answered.

16           **A**     In 2014, I believe that people are learning  
17 those procedures.

18           **Q**     (By Mr. Kuntz) Right. Well, the medical  
19 school that you trained at and went to still teaches  
20 both, correct?

21           **A**     Well, I did my fellowship at Duke  
22 University. I didn't do medical school there. I  
23 went to medical school at Temple University, and I  
24 don't have as close ties to Temple. So I'm not aware  
25 of what they do at Temple University at this point.

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1           **Q**     But Duke University still teaches the Burch  
2     and pubovaginal sling?

3           **A**     I would agree with that.

4           **Q**     And they still offer the Burch and  
5     pubovaginal sling?

6                   MR. SNELL: Objection, foundation, vague.

7           **A**     I suspect they do. I have no reason to  
8     believe they don't.

9           **Q**     (By Mr. Kuntz) What are all the hospitals  
10    you have current privileges at?

11          **A**     All of them are in Colorado, and all of  
12    them are within our network. It's -- the University  
13    of Colorado Hospital, that's where I spend 95 percent  
14    of my time. Veterans Administration Hospital in  
15    Denver. The Denver Health Medical Center, which is  
16    in Denver. It's a public hospital in Denver. And  
17    then The Children's Hospital of Colorado.

18          **Q**     Have you ever had your privileges revoked  
19    or suspended or limited in any way?

20          **A**     No.

21          **Q**     Have you ever been sued for malpractice?

22          **A**     Yes.

23          **Q**     How many times?

24          **A**     At least two or three times.

25          **Q**     Any of those cases involve pelvic mesh?

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1           **A**       No.

2                   MR. SNELL: Jeff, can we take another break  
3 whenever you get to a good stopping point. Our food  
4 has been here for a while.

5                   MR. KUNTZ: No, that's fine. Take a break.

6                   (Recess from 4:06 p.m. to 4:45 p.m.)

7                   (Exhibits 6 through 28 were marked.)

8           **Q**       (By Mr. Kuntz) Doctor, I think when we  
9 left off you were telling me about your malpractice  
10 claims and said none had involved pelvic mesh.

11           **A**       Personal malpractice claims against me?

12           **Q**       Yes.

13           **A**       That's correct.

14           **Q**       What were the issues in the three  
15 malpractice cases against you?

16           **A**       The first case was a case that a guy had  
17 some issues with the way his penis looked after an  
18 urethroplasty operation. That was a male patient,  
19 and they never followed through with the lawsuit. So  
20 nothing came of that.

21                   Second case was a patient who we -- it  
22 really wasn't a lawsuit, but we did reach settlement.  
23 We settled with the patient before there ever was a  
24 lawsuit, and that was a patient who had complications  
25 from insertion of an artificial urinary sphincter

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1 device.

2 Third case was a patient that had alleged  
3 that there was a delay in diagnosis of cancer, and he  
4 never pursued the case. He filed it but never  
5 pursued it.

6 Q Prior to using the TVT Retropubic device,  
7 what devices did you use to treat stress urinary  
8 incontinence?

9 A So you're speaking of what I did from 2002  
10 to 2004 at my own practice?

11 Q Correct.

12 A I used the American Medical Systems Sparc.  
13 I used the American Medical Systems BioArk. I used  
14 the allograft fascia and autologous fascia to do  
15 pubovaginal sling. And I did bulking agents using  
16 collagen.

17 MR. KEITH: Jeff, let's stop and go off the  
18 record for one second.

19 (Discussion off the record.)

20 Q (By Mr. Kuntz) Did you ever use the  
21 Protegen device, Doctor?

22 A No. That existed before I had graduated.

23 Q I want to talk about revisions performed by  
24 you. How many mesh revisions did you perform in the  
25 year 2014?

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1           **A**       2014. So in this past year?

2           **Q**       Yes.

3           **A**       Somewhere in and around 40 to 50.

4           **Q**       Did you do, actually, any revisions where  
5 you removed the entire mesh?

6           **A**       Yes.

7           **Q**       How many?

8           **A**       About four or five.

9           **Q**       Were these all your patients or patients  
10 that were referred to you?

11          **A**       This year I would say probably 99 percent.  
12 So if the number was 50, I would say 47 or 48 were  
13 referred to me.

14          **Q**       Did the referring -- well, strike that.

15                    To your knowledge, did the implanting  
16 physicians, who put that mesh in, know you were doing  
17 revision or removal surgeries on their patients?

18          **A**       Most of them did.

19          **Q**       How do you know that?

20          **A**       I communicated with them by phone, by fax,  
21 by e-mail, by written communication in terms of  
22 getting a referral from them for the problem and  
23 sending communication back to them.

24                    The ones that I didn't have communication  
25 with were usually someone who maybe moved into the

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1 area and their original surgery was out of state and  
2 I didn't know that referring physician or have any  
3 relationship with them.

4 Q Do you know how many TVT Abbrevos that  
5 you've revised or removed?

6 A In 2014?

7 Q In 2014.

8 A Maybe one or two.

9 Q How many revisions did you perform in 2013  
10 of all the SUI products?

11 A Somewhere around 40.

12 Q Do you know how many of those were TVT  
13 products?

14 A The whole family of products?

15 Q Yeah, the whole family of products.

16 A Probably about one-quarter of them. So 10.

17 Q And I don't think I asked this. The same  
18 question. 2004 (sic) after -- from the 50 revisions  
19 you did, do you know how many were out of the TVT  
20 line of products?

21 A In 2014?

22 Q Yes.

23 A Well, I'd like to be clear on that. I  
24 would say each year it was -- about 25 percent were  
25 Ethicon products, and of the 50, I'm speaking of all

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1 transvaginal mesh, both for prolapse, as well as for  
2 incontinence.

3 Q So your 50 revisions in 2014 included  
4 slings and POP products?

5 A That's correct.

6 Q Do you know how many were slings versus  
7 POP?

8 A It's about 50/50. So let's say 25 for POP;  
9 25 for sling surgery. In really all of the years,  
10 that's been a pretty consistent number.

11 Q Okay. So for every year, it's been about  
12 half and half POP -- half POP revisions and half  
13 sling revisions?

14 A Yes.

15 Q In 2013, you did 40 revisions you think.  
16 How about in 2012?

17 A Less than that. Maybe 30 or so. 38, 35.  
18 It's in that article that I published in  
19 International Urogynecology. There's a bar graph --  
20 not a bar graph. There's a scatter plot, if you  
21 will, showing it. If I can refer to that, I can give  
22 you more precise numbers.

23 So I'm opening that up, and I believe we  
24 marked it as Exhibit 4. So let's look at -- well,  
25 the data goes to 2012. It looks like there was a

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1 total of 50.

2 So I would say from 2012, 2013, 2014 it's  
3 plateaued. I've been doing about 50 cases a year for  
4 the last three years.

5 Q Have the number of revisions in  
6 complications increased in the last three years?

7 MR. SNELL: Objection, compound.

8 A No.

9 Q (By Mr. Kuntz) Okay. So you believe there  
10 are the same amount of mesh complications in, say,  
11 2011 as there is in 2014?

12 A 2012, '13, and '14 I believe are the same.  
13 2011, I have 40. 2012, there was 50. And then  
14 that's where it plateaued at 2012.

15 Q What about 2010?

16 A 2010, it looks like there's around 26, 27.

17 Q 2009?

18 A Similar amount. 27, maybe 28.

19 Q 2008?

20 A 2008, it was around 18.

21 Q Have you ever performed a revision surgery  
22 because the patient was reporting pain?

23 A Yes. That's the primary reason.

24 Q Okay. Have you ever done a revision  
25 surgery because the patient was reporting

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1 dyspareunia?

2 **A** Yes.

3 **Q** Have you ever performed a revision surgery  
4 because the patient suffered an erosion?

5 **A** Exposure through the vaginal wall?

6 **Q** An exposure through the vaginal wall.

7 **A** Yes.

8 **Q** What do you believe Mrs. Perry had?

9 **A** She had an exposure through the vaginal  
10 wall, vaginal mesh exposure.

11 **Q** Are you doing as many surgeries now to  
12 treat mesh complications as you are implanting  
13 meshes?

14 **A** No.

15 **Q** What do you think the ratio is?

16 **A** For incontinence or prolapse?

17 **Q** Incontinence.

18 **A** With respect to incontinence, I would say  
19 in 2014, you know, we did 50 mesh revisions, 25 for  
20 incontinence, 25 for prolapse. And I probably did in  
21 and around 80 to 100 SUI surgeries. So that ratio  
22 would be close to two to one, I guess.

23 **Q** And is that incontinence surgeries with a  
24 mesh device that are 80 to 100?

25 **A** No. 50 percent of my incontinence

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1 surgeries involve mesh. 50 percent don't.

2 Q Okay. So we can say 40 to 50 SUI mesh  
3 placements a year and 25 revisions of mesh SUI  
4 surgeries a year?

5 A Yeah. So still at around two to one. Say  
6 25 SUI mesh sling revisions and 50 or so primary  
7 implants.

8 Q And you obviously believe all those  
9 revision surgeries you did were medically necessary,  
10 correct?

11 A I felt strongly about the indication, and  
12 the patients desired me to do the surgery, so yes.

13 Q Did you know whether any of those patients  
14 were involved in litigation against a mesh  
15 manufacturer?

16 A Yeah. I'm aware of at least, say, 8 or 10  
17 patients.

18 Q And you performed surgery on them because  
19 you thought it was medically necessary and not  
20 because of a lawsuit, correct?

21 MR. SNELL: Objection, form, asked and  
22 answered. It misstates.

23 A I felt that the indications were valid.

24 Q (By Mr. Kuntz) When did you start teaching  
25 mesh complications courses at society organizations

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1 or conventions?

2 **A** I've given lectures. I haven't taught  
3 courses. I think there's a big difference between  
4 those two things.

5 **Q** Okay. Well, when did you start giving  
6 lectures?

7 **A** I'm going to look at my CV to give you the  
8 exact date. So if I have a moment here.

9 (Pause.)

10 **A** It looks like somewhere in and around 2008.

11 **Q** Is the first time you gave a lecture on the  
12 treatment of mesh complications?

13 **A** Yes. I've given lectures previous on  
14 complications from other type of surgeries more  
15 related to male incontinence, but specific for, you  
16 know, female prolapse and incontinence surgery  
17 procedures involving mesh, 2008.

18 **Q** Have you ever given any lectures on  
19 long-term mesh -- or strike that.

20 Have you ever given any lectures on  
21 complications related to the Burch procedure?

22 **A** Yes.

23 **Q** And when was that?

24 **A** That was the same lecture. So that lecture  
25 was entitled Surgical -- or I'm sorry --

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1 Complications of Prolapse and Incontinence Surgery, a  
2 Step-wise Approach, Jackson Hole Seminars, February  
3 2006. That was one lecture.

4 Q Where was that -- who was that lecture for?

5 A That was --

6 MR. SNELL: Form, compound. Go ahead.

7 A -- a group of urologists at a meeting in  
8 Jackson Hole, Wyoming. Probably about 80 to 100  
9 people in attendance.

10 Q (By Mr. Kuntz) Who sponsored the lecture?

11 A There's no sponsor. It's -- it's a  
12 scientific meeting, a seminar. It's a seven-day  
13 meeting. That was one of six talks I gave there as  
14 an invited speaker. It wasn't sponsored by industry.

15 Q Did you bring that lecture with you today?

16 A I believe that's on the USB.

17 Q What do you believe the long-term  
18 complications for the Burch procedure are?

19 A Probably the biggest one would be voiding  
20 dysfunction. So the Burch procedure could be too  
21 tight, and then that could lead to urethral  
22 obstruction, which results in urinary retention,  
23 bladder incomplete emptying, and eventual bladder  
24 decompensation.

25 Q What else?

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1           **A**       Other risks with the procedure could be  
2       suture perforation through the vaginal wall, suture  
3       perforation into the urethra or into the bladder.  
4       There can be wound-related complications, wound  
5       dehiscence, seroma, hernia, wound pain.

6           If the procedure is done laproscopically,  
7       there could be laproscopic-related complications from  
8       trocars, such as bowel injury, injuries related to  
9       the CO2 insufflation into the abdomen. But the main  
10      ones center around voiding dysfunction.

11          **Q**       Do you believe that chronic or long-term  
12      dyspareunia is a risk with the Burch procedure?

13          **A**       I would say it's a very small risk, but  
14      yes, it's a risk.

15          **Q**       Do you have any literature to support that  
16      it is a risk?

17          **A**       I don't have anything in front of me. Let  
18      me take a look at my Summary of Opinions.

19                I don't -- I think it would be rare, but,  
20      you know, if you had a suture perforate through the  
21      vaginal wall, then potentially that could cause  
22      dyspareunia. That seems logical to me.

23          **Q**       As you sit here today, you don't have any  
24      literature on your Summary of Opinions and you can't  
25      recall any that talks about chronic or long-term

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1 dyspareunia being a risk of the Burch procedure --

2 MR. SNELL: Objection, form.

3 Q (By Mr. Kuntz) -- correct?

4 MR. SNELL: Objection, form. It misstates.

5 A I don't have that in my Summary of  
6 Opinions, and I can't think of an article offhand,  
7 no.

8 Q (By Mr. Kuntz) Okay. Do you believe that  
9 chronic, long-term pain is a risk of the Burch  
10 procedure?

11 A Potentially, yes.

12 Q Do you have any literature to support your  
13 opinion or can you cite me any literature to support  
14 your opinion that chronic pain is a risk of the Burch  
15 procedure?

16 MR. SNELL: If you need to go through your  
17 materials, you can go through them.

18 A I'm going to just take a look at my  
19 materials here.

20 Q (By Mr. Kuntz) Okay.

21 MR. KEITH: Just for the record, he's  
22 looking through materials that are contained in the  
23 orange folder, which is Exhibit 8, I think.

24 (Pause.)

25 A I don't -- I don't see anything in front of

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1 me in terms of an article on Burch reporting  
2 dyspareunia.

3 Q (By Mr. Kuntz) And I think we talked about  
4 that before, but my question was: Show me any  
5 literature you brought or relied on or remember  
6 reading that chronic, long-term pain is a risk  
7 associated with the Burch procedure.

8 A Okay. I can't produce that.

9 Q Okay.

10 MR. SNELL: You can go through your  
11 materials, if you want to, and take your time. He's  
12 asking for a specific article.

13 Q (By Mr. Kuntz) Doctor, did you review  
14 every single document you brought with you today or  
15 that was supplied to you by plaintiff's counsel?

16 A I have, but, you know, it's been over a  
17 six-month period, as I mentioned earlier, and there's  
18 probably well over 4- or 500 articles in front of me  
19 here. So I'm sorry if I'm a little slow in producing  
20 things.

21 Q No. That's all right. And you reviewed  
22 all of those articles -- 4- or 500 articles, and they  
23 form the basis of your opinion in the -- I think you  
24 told me 45 -- 55 hours you spent reviewing this case,  
25 you reviewed all 400 articles?

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1           **A**       No. Some of the --

2                   MR. SNELL: Hold on. Objection. It  
3 misstates. Also, asked and answered. Go ahead.

4           **A**       Some of the articles are articles that I've  
5 had for years and articles that I may have already  
6 been familiar with well before I agreed to be an  
7 expert in this case.

8           **Q**       (By Mr. Kuntz) Have you ever told -- when  
9 you're giving lectures or teaching at AUGS, that  
10 there's papers out there that suggest that with the  
11 Burch procedure, you can have long-term, chronic  
12 pain?

13          **A**       I wouldn't have referenced the Burch  
14 procedure specifically, but certainly I've mentioned  
15 that long-term, chronic pain or dyspareunia is a risk  
16 of any incontinence and prolapse surgery.

17          **Q**       Do you have any literature to specifically  
18 support those opinions, that long-term dyspareunia or  
19 chronic pain are associated with the Burch procedure?  
20 You can't cite me any as we sit here in your depo  
21 today?

22          **A**       That's correct.

23          **Q**       Okay. And you would agree with me that  
24 chronic pain can be associated with the implantation  
25 mesh SUI device, correct?

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1 MR. SNELL: Objection, form. Go ahead.

2 A Incorrect.

3 Q (By Mr. Kuntz) You don't believe that  
4 long-term pain is an adverse risk associated with the  
5 placement of mesh?

6 MR. SNELL: Objection, form, application.  
7 It misstates the prior testimony. Go ahead.

8 A I believe the issue is with transient pain  
9 and then pain related to exposure or perforation  
10 that's untreated.

11 Q (By Mr. Kuntz) So do you -- I mean, can  
12 you answer my question, Doctor? Do you believe  
13 there's long-term pain associated with the placement  
14 of mesh SUI devices?

15 MR. SNELL: Objection, form, asked and  
16 answered.

17 A Yeah, I believe I've already answered that.  
18 So I'm not going to answer that again.

19 Q (By Mr. Kuntz) Well, what's the answer to  
20 the question?

21 A My answer was that I think if it's  
22 associated with a complication -- if the mesh is  
23 associated with the complication, then you can have  
24 long-term pain, but I think the way you stated that  
25 was overly broad.

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1           So, you know, mesh implants, in general, I  
2   don't find associated with chronic pain. If someone  
3   has a foreign body in the urinary tract, then that  
4   can cause them pain.

5           **Q**     What if somebody has an exposure through  
6   their vaginal wall, can they have long-term pain?

7           **A**     If it's untreated, yes.

8           **Q**     Does the University of Colorado have a  
9   center set up to deal with mesh complications?

10          **A**     We have physicians that see patients with  
11   those issues, but we don't have a dedicated center.

12          **Q**     Do you advertise for those sort of  
13   complications on your Web site?

14          **A**     We list on our Web site what procedures we  
15   perform, but we don't -- I wouldn't consider it an  
16   advertisement.

17          **Q**     Do you know of any university centers in  
18   the United States who are now refusing to use mesh  
19   products?

20                 MR. SNELL: Objection, foundation.

21          **A**     I have heard that Mayo Clinic maybe, but  
22   it's -- it wasn't from personal communication with  
23   any colleagues there. Just, you know, what I've  
24   heard through various people.

25          **Q**     (By Mr. Kuntz) Have you heard of any

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1 centers that are refusing now to use mesh?

2 MR. SNELL: Objection, vague as to  
3 application.

4 A Yeah.

5 Q (By Mr. Kuntz) Well, Doctor, you go to  
6 AUGS meetings and a lot of society meetings, and you  
7 talk to colleagues all the time, don't you?

8 A I do go to some AUGS meetings, but I am a  
9 urologist by trade. I tend to go to -- SUFU and AUA  
10 are the meetings I more regularly attend. I maybe go  
11 to AUGS once every four or five years.

12 Q Okay. Any meetings you go to, have you  
13 ever had discussions with anybody about major US  
14 universities who are no longer using mesh?

15 A No.

16 Q Okay. Have you ever heard that from  
17 anybody?

18 A Yeah.

19 MR. SNELL: Form -- hold on. Form, vague,  
20 overbroad.

21 A I did hear that about the Mayo Clinic, but  
22 that wasn't at a meeting.

23 Q (By Mr. Kuntz) So is the Mayo Clinic the  
24 only institution you've heard about that has stopped  
25 using mesh?

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1 MR. SNELL: Objection, form, overbroad,  
2 lacks foundation as to "Mayo Clinic stopping using  
3 mesh" in general.

4 Q (By Mr. Kuntz) Let me ask you this,  
5 Doctor: Have you ever seen any internal Ethicon  
6 documents that talk about different centers in the  
7 U.S. that have stopped using mesh?

8 A No.

9 MR. SNELL: Objection, form. Overbroad as  
10 to application, just "mesh."

11 A I have not.

12 Q (By Mr. Kuntz) Okay. Are you aware of any  
13 countries in the world that have stopped using mesh?

14 MR. SNELL: Same objection.

15 A No.

16 Q (By Mr. Kuntz) Have you ever done any  
17 research to see if there are centers in the United  
18 States who have stopped using mesh?

19 MR. SNELL: Same objection, "mesh," vague.

20 A I'm aware of research and articles looking  
21 at practice patterns of physicians.

22 Q (By Mr. Kuntz) And what articles are  
23 those?

24 A I believe Howard Goldman did a study  
25 looking at practice patterns in the United States,

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1 and I don't have the article in front of me right  
2 now, but I have reviewed that recently, where it had  
3 mentioned that as many as 95 percent of physicians  
4 performing mid-urethral sling, in terms of those  
5 physicians who treat stress urinary incontinence, as  
6 opposed to only 5 percent of physicians doing the  
7 Burch procedure or other more traditional procedures.

8 Q Do you know when that study was published?

9 A I believe that's fairly recent. In 2014,  
10 in International Urogynecology Journal, I believe.

11 Q And did you read any of the study sites in  
12 that paper as to where they came up with that number?

13 A I would have to go back and look at that  
14 again to see where he got that number, but I believe  
15 it was either from survey data or from looking at the  
16 Medicare data.

17 Q Have you ever reviewed the Clemons article  
18 that's cited in the AUGS position statement?

19 A I'd have to see that article. I may have.  
20 I'm familiar with Dr. Clemons, and I'm familiar with  
21 the AUGS statement, but I'm not certain which article  
22 you're referring to.

23 Q Well, I'm talking about the Clemons article  
24 that you list in your Summary of Opinions and that's  
25 cited in the AUGS statement. Have you reviewed that

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1 article?

2 **A** Yeah. The article from 2013?

3 **Q** Yes.

4 **A** Yes.

5 **Q** Okay. Were you aware that Scotland has  
6 suspended the use of all mesh, including synthetic --  
7 or strike that.

8 Are you aware that Scotland has suspended  
9 the use of all mesh even for SUI products?

10 MR. SNELL: Foundation objection. Go  
11 ahead.

12 **A** I'm familiar with the N-I-C-E, the NICE  
13 data --

14 **Q** (By Mr. Kuntz) Right.

15 **A** -- but I'm not familiar specific to what  
16 they're doing in Scotland but maybe the UK as a  
17 whole.

18 **Q** So you're familiar with the NICE  
19 guidelines?

20 **A** I am.

21 **Q** And you've read those thoroughly?

22 **A** I've read them, yes.

23 **Q** And I think they support some of your  
24 opinions in this case that the mid-urethral sling is  
25 the gold standard?

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1           **A**       That's correct.

2           **Q**       And you've relied on that document to  
3       support that opinion, correct?

4           **A**       Correct.

5           **Q**       And which NICE guidelines did you review?  
6       When were they issued?

7           **A**       Let me go ahead and pull it out of the  
8       orange folder here.

9           **Q**       Sure.

10           MR. KEITH: Doc, tell me what exhibit  
11       number that orange folder is so we're clear. It's on  
12       the front of the orange folder.

13           THE DEPONENT: Eight.

14           MR. KEITH: Eight. Okay.

15           **A**       But now I'm going into Exhibit 6. This is  
16       one of the black binders, and Exhibit 6 starts out  
17       with the AUGS statement, then goes into the NICE  
18       2013, Urinary Incontinence -- The Management of  
19       Urinary Incontinence, issued September 2013.

20           **Q**       (By Mr. Kuntz) But no knowledge, as we sit  
21       here today, that Scotland suspended the use of --  
22                       (Reporter requested clarification.)

23           **Q**       (By Mr. Kuntz) But today -- as we sit here  
24       today, you've never been provided or have no  
25       knowledge about Scotland's decision to suspend the

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1 use of all mesh, including that mesh in stress  
2 urinary incontinence products?

3 MR. SNELL: Objection, foundation. Go  
4 ahead.

5 A I'm not aware specific of what Scotland's  
6 position is. So that's correct. I'm not aware of  
7 it. I shouldn't say -- I'm unaware of that, sir.

8 Q (By Mr. Kuntz) Do you believe the Abbrevio  
9 product uses the transobturator approach?

10 A Certainly.

11 Q And would you agree that there's a lack of  
12 long-term outcome data for transobturator-approach --

13 MR. SNELL: Objection, form.

14 Q (By Mr. Kuntz) -- slings?

15 A I would disagree.

16 Q You disagree with that statement?

17 A I do. I disagree with that statement.

18 Q Okay. Do you disagree with the statement  
19 in the AUGS position statement that says, "Data is  
20 only good for up to one year"?

21 MR. SNELL: Objection, form and foundation.  
22 It misstates the document.

23 Q (By Mr. Kuntz) Well, let's pull it out.

24 A Okay. Let's pull it out. I'm aware of  
25 Dr. de Leval's data going out more than three years

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1 for TVT obturator.

2 Q Have you ever seen any internal documents  
3 from Ethicon talking about the deficiencies or  
4 problems with Dr. de Leval's TVT-O studies?

5 A No.

6 Q Those weren't provided to you?

7 MR. SNELL: Form objection --

8 A I don't have --

9 MR. SNELL: -- foundation.

10 A I don't have those.

11 Q (By Mr. Kuntz) So no documents discussing  
12 the decision in Dr. de Leval's TVT-O studies were --  
13 formed the basis for your opinions in this case,  
14 correct?

15 A Correct.

16 Q Do you have the AUGS statement in front of  
17 you?

18 A The position statement on restriction of  
19 surgical options for pelvic floor disorders.

20 Q Let me find the right one. The 2014  
21 position statement.

22 I apologize. I can't find my copy. I have  
23 to find it. Give me one second. Do you guys have a  
24 copy of it there?

25 MR. SNELL: Which one were you talking

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1 about, Jeff? You said the --

2 MR. KUNTZ: The AUGS --

3 MR. SNELL: -- two thousand --

4 MR. KUNTZ: -- one. 14, position

5 statement. The one you used in every trial a hundred  
6 times.

7 MR. SNELL: Let's see if I have it. I  
8 don't know which one that is. I'm trying to see if  
9 we have one printed out here. The problem is, we've  
10 got like -- he's got like a million documents all  
11 over this table, and it's kind of getting  
12 unmanageable with all this crap here.

13 MR. KUNTZ: Well, I will get one on the  
14 break.

15 MR. KEITH: I don't have one in the folder,  
16 do I, or the box?

17 MR. KUNTZ: I thought we did, but maybe  
18 not. Maybe it didn't make its way in there.

19 MR. SNELL: The AUGS/SUFU statement -- the  
20 position statement --

21 MR. KUNTZ: Yeah.

22 MR. SNELL: -- that's the one you want?

23 MR. KUNTZ: Yeah.

24 MR. SNELL: Okay.

25 MR. KUNTZ: Yeah. I'm going to have to get

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1 my copy, so I'll come back to it.

2 Q (By Mr. Kuntz) Doctor, do you believe --  
3 and I think you state in your opinions that the TVT  
4 Abbrevio is the gold standard?

5 A I believe I said that the TVT is the gold  
6 standard, the family. I think that the TVT Abbrevio  
7 is an obturator sling, and it can be included in that  
8 conversation.

9 Q What's your definition of "gold standard"?

10 A "Gold standard" is probably an overutilized  
11 term, but it's not the standard of care. It's  
12 probably just reflective of what's done most commonly  
13 and what's the most reliable procedure.

14 Q Doesn't gold standard mean there's only one  
15 thing that can be the gold standard?

16 A Not necessarily.

17 Q Okay. So you believe that the TVT Classic  
18 or Retropubic is the gold standard, you believe the  
19 TVT Abbrevio is the gold standard, you believe the TVT  
20 Obturator is the gold standard, and you believe the  
21 TVT Exact is the gold standard, correct?

22 A I believe that those are all effective  
23 procedures similar to what's stated in the SUFU/AUGS  
24 statement, that I believe that the mid-urethral  
25 sling, both retropubic and transobturator, have been

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1 extensively studied. They're safe and effective,  
2 reliable treatments.

3 I know that from the literature, and I know  
4 that from my own practice.

5 Q How many studies have there been done on  
6 the TVT Abbrevio?

7 A I know of at least seven to eight good  
8 studies that have been done.

9 Q And what studies -- are those studies you  
10 brought with you?

11 A I have copies of them, yeah, and they've  
12 been submitted on the -- on the USB, but, you know,  
13 for --

14 Q Do you believe that the AUGS statement  
15 applies to the TVT Abbrevio?

16 A I do because I believe the TVT Abbrevio  
17 meets the criteria of the transobturator sling.

18 Q Okay. You would agree with me that the  
19 AUGS statement only applies to full-length slings,  
20 correct?

21 MR. SNELL: Form, misstates.

22 Q (By Mr. Kuntz) Do you know that one way or  
23 the other?

24 A I believe in their justification -- in  
25 Statement No. 3, it says, "Full-length mid-urethral

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1 slings."

2 Q And do you believe that TVT Abbrevio is a  
3 full-length sling?

4 A I believe it's in its own category, really,  
5 but it's a transobturator sling that courses through  
6 all the necessary structures in the obturator  
7 foramen.

8 So what doesn't it do? It doesn't go into  
9 the fat and skin maybe like a TVT Obturator  
10 full-length.

11 Q Doctor, that's not my question. Do you  
12 think the TVT Abbrevio is a full-length sling?

13 A I would have to --

14 Q That's a "yes" or "no" question.

15 A All right. No. I would say no.

16 MR. SNELL: Objection, form.

17 Q (By Mr. Kuntz) No --

18 MR. SNELL: He can answer how he wants.

19 It's not a "yes" or "no."

20 MR. KUNTZ: Oh, yes, it is.

21 Q (By Mr. Kuntz) You just said "no" -- the  
22 answer to the question is "no," correct, Doctor?

23 MR. SNELL: Same objection, asked and  
24 answered.

25 Q (By Mr. Kuntz) I asked you --

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1 MR. KUNTZ: No, Burt. Absolutely not. It  
2 is a "yes" or "no" question.

3 Q (By Mr. Kuntz) Is the TVT Abbrevio a  
4 full-length sling, Doctor?

5 MR. SNELL: Objection, form, asked and  
6 answered. Go ahead.

7 A I said no. I would like to say that, you  
8 know, it's a 12-centimeter sling. I think it's  
9 plenty long.

10 Q (By Mr. Kuntz) Okay. So what is the  
11 length of the TVT Abbrevio?

12 A 12 centimeters.

13 Q Okay. What is the length of a TVT-O?

14 A Out of the box or what's left in the  
15 patient?

16 Q Both.

17 A Out of the box is 45 centimeters. What's  
18 typically left in the patient is around 18  
19 centimeters, somewhere between 15 and 18 centimeters.

20 Q Do you know -- do you know how Ethicon  
21 defines -- strike that.

22 Do you have any knowledge as to what --  
23 strike that again. I apologize.

24 Do you have any idea of what Ethicon's  
25 definition of "mini sling" is?

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1           **A**     I believe they followed what the FDA said.  
2     Mini slings need 522s, and that would be the TVT  
3     Secur. So 8 centimeters or less.

4           **Q**     Okay. So you believe Ethicon's definition  
5     of "mini sling" is 8 centimeters or less?

6           **A**     That's my general understanding of it.

7           **Q**     Have you ever seen any internal documents  
8     where Ethicon defines what they believe to be the  
9     parameters of a mini sling?

10          **A**     No.

11          **Q**     Have you ever reviewed any Ethicon  
12     documents that called the Abbrevio a mini sling?

13          **A**     No.

14          **Q**     You would agree that the safety and  
15     effectiveness of mini slings for female SUI has not  
16     been adequately demonstrated? Is that a fair  
17     statement?

18                 MR. SNELL: Objection, form, vague,  
19     foundation.

20          **Q**     (By Mr. Kuntz) Let me ask you this,  
21     Doctor: Have you ever been on the FDA Web site to  
22     see what they say about mini slings?

23          **A**     I've read the FDA, PHN, and the update.  
24     I'm aware of those statements.

25          **Q**     Okay. Are you aware of the FDA statement

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1 that says, "The safety and effectiveness of mini  
2 slings for female SUI has not been adequately  
3 demonstrated"?

4 **A** Yes.

5 **Q** Okay. Do you agree with the FDA on that  
6 statement?

7 **A** Yes.

8 **Q** You no longer use the TVT Retropubic,  
9 correct?

10 MR. SNELL: Objection, form, asked and  
11 answered.

12 **A** Yeah.

13 **Q** (By Mr. Kuntz) You still believe the TVT  
14 Retropubic is the gold standard, and you don't use  
15 it, right, Doctor?

16 **A** I use the TVT Exact, and that's a  
17 retropubic tape. And I feel that that is part of  
18 that family of products that we mentioned that are,  
19 you know, mid-urethral slings, either retropubic or  
20 transobturator.

21 I put it all together. I don't try to  
22 separate these products the way you are trying to do.

23 **Q** And that's my point. The AUGS statement is  
24 talking about many different products, and it doesn't  
25 separate them, does it?

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1           **A**       The AUGS statement says both retropubic and  
2       transobturator. I think that's where they try to  
3       have the separation, between retropubic and  
4       transobturator.

5           **Q**       And transobturator full-length sling,  
6       correct?

7           **A**       The statement says, "Full-length  
8       mid-urethral slings."

9           **Q**       Okay. Do you know any of the authors of  
10      the AUGS position statement?

11          **A**       I do.

12          **Q**       Did you know that Dr. Goldman has had  
13      consulting agreements with Ethicon in the past?

14               MR. SNELL: Foundation objection. Go  
15      ahead.

16          **A**       I've interacted with Dr. Goldman at Ethicon  
17      events. So I would assume that he had a relationship  
18      if he was at the same events I was at.

19          **Q**       (By Mr. Kuntz) Did you know that  
20      Dr. Miller had previous consulting agreements and  
21      relationships with Ethicon?

22          **A**       I was aware that he had consulted with  
23      Boston Scientific, but I didn't know about Ethicon.

24          **Q**       Do you know Dr. Rovner has had financial  
25      dealings and dealings with Ethicon?

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1 MR. SNELL: Form, foundation. Go ahead.

2 A I have reviewed Dr. Rovner's deposition,  
3 and I did see that in his deposition.

4 Q (By Mr. Kuntz) Did you also see in  
5 Dr. Rovner's deposition where he's now doing more  
6 mesh revisions and complication surgeries than he is  
7 implanting meshes?

8 A I don't recall that statement.

9 Q Would that surprise you?

10 MR. SNELL: Foundation, form.

11 A I know that he has experience with that. I  
12 was part of a plenary session at the AUA this past  
13 year with Dr. Rovner and Dr. Sendor Herschorn. The  
14 three of us did a session at the AUA in the spring of  
15 this year.

16 So I'm familiar with him doing complication  
17 surgery, but I don't know what percentage that is of  
18 his overall practice.

19 Q (By Mr. Kuntz) You don't recall reading  
20 that in his deposition one way or another?

21 A I don't recall reading that one way or  
22 another.

23 Q I'm going to ask you about a few products,  
24 and tell me which one you believe is the gold  
25 standard. Mechanical-cut mesh TVT Retropubic. Gold

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1 standard?

2 MR. SNELL: Form objection, vague.

3 A I can't answer that.

4 Q (By Mr. Kuntz) Why not?

5 A Because I think I mentioned earlier there's  
6 more than one gold standard. That's a family of  
7 products that go across various manufacturers that  
8 are part of that gold standard.

9 So if you ask me that question about any  
10 mid-urethral transobturator or retropubic  
11 polypropylene Type 1 mesh, I would say it's a gold  
12 standard that meets the criteria of a mid-urethral  
13 sling as defined by the AUA, by AUGS, and by NICE.

14 Q Have you ever seen any AUA documents that  
15 suggest that there's not adequate evidence to suggest  
16 which procedure for SUI treatment is the best?

17 MR. SNELL: Form, vague.

18 A I think the AUA takes a very balanced  
19 approach. I think they -- if you look at the '98  
20 article and then in 2008, they look across all  
21 procedures, including the Burch, bladder neck slings,  
22 pubovaginal slings. And I think they -- they are  
23 very careful to just present the data in terms of  
24 what the risks and benefits are.

25 Q (By Mr. Kuntz) So do you believe the AUA

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1 thinks that mid-urethral slings are the gold standard  
2 for SUI treatment?

3 **A** I would say that the AUA endorses that  
4 procedure and is very comfortable standing behind  
5 that procedure. They put out a position statement in  
6 those regards, so they are supportive of the  
7 procedure.

8 **Q** Do they believe it's the gold standard?

9 **A** I don't think they use that terminology,  
10 but none of the professional societies use the  
11 statement "gold standard."

12 **Q** So AUGS doesn't use "the gold standard" in  
13 their last position statement? Is that your  
14 understanding?

15 **A** I would have to read every word of it  
16 again, but it says, "Both retropubic" --

17 (Reporter asked the deponent to slow down.)

18 **A** "Full-length mid-urethral slings both" --

19 (Reporter asked the deponent to slow down.)

20 **A** So I'll slow down and repeat that just for  
21 the court reporter.

22 You know, "FDA clearly stated that  
23 polypropylene mid-urethral sling is safe and  
24 effective in the treatment of SUI."

25 **Q** (By Mr. Kuntz) With information up to one

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1 year, correct?

2           **A**     No, I believe the information goes well  
3 beyond one year.

4           **Q**     What's your basis for that opinion, Doctor?

5           **A**     That basis is on my review of over 75  
6 randomized trials and over 2,000 articles in the  
7 medical literature over the last 15 years.

8           **Q**     Tell me which 2,000 of those articles apply  
9 to the product at issue in this case, the TVT  
10 Abbrevio.

11          **A**     So if we want to start with TVT Abbrevio  
12 articles, we can start with the --

13          **Q**     Let's strike that.

14                 You agree that there's not 1,000 studies  
15 that address the TVT Abbrevio, correct?

16                 MR. SNELL: Objection, form, vague,  
17 "address."

18          **A**     There's not 1,000 studies on TVT Abbrevio.

19          **Q**     (By Mr. Kuntz) Yeah. There's how many?

20          **A**     8 to 10.

21          **Q**     Okay. Are any of those 8 to 10 studies  
22 long-term randomized controlled trials?

23          **A**     Well, I believe the Waltregny 2012 study  
24 has three-year data. So that's -- I consider three  
25 years a longer long-term.

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1           **Q**     Is that the paper he published  
2     with de Leval?

3           **A**     I know de Leval had a separate publication  
4     in 2011. Let me see if de Leval was a coauthor on  
5     that.

6                     (Pause.)

7           **A**     I don't know the answer, if de Leval was  
8     part of that. I don't have the article in front of  
9     me.

10          **Q**     Okay. Did you read de Leval's three-year  
11     publication or study?

12          **A**     Comparing TVT Abbrevio to TVT Obturator,  
13     yes.

14          **Q**     Have you read his original study tracking  
15     -- three-year study tracking his modified TVT-O,  
16     which was the -- supposedly the Abbrevio?

17                     MR. SNELL: Form and foundation.

18          **A**     I've read the study where  
19     Professor de Leval compares TVT Abbrevio to TVT  
20     Obturator. That's the study I'm referring to.

21          **Q**     (By Mr. Kuntz) Did you know that his  
22     one-year study related to that comparison was  
23     initially rejected by publications?

24          **A**     I wasn't aware of that, but that's not  
25     uncommon.

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1           **Q**     So you didn't know that, right?

2           **A**     I have no way of knowing that, no.

3           **Q**     Do you know how many products in that study  
4     were laser-cut versus mechanical-cut mesh?

5           **A**     Well, all of the TVT Abbrevio products would  
6     have been laser-cut. That's how that product was  
7     offered from the beginning.

8           **Q**     So that's your understanding, that all the  
9     Abbrevio's in that study was laser-cut mesh?

10          **A**     That's my general understanding.

11          **Q**     Have you ever seen any documents or been  
12     provided any documents by Ethicon's counsel  
13     suggesting otherwise?

14          **A**     No.

15          **Q**     Was that a single-center study; do you  
16     know?

17          **A**     I suspect it was, but I don't know for  
18     sure.

19          **Q**     Have you ever seen any documents from  
20     Ethicon that Dr. de Leval was concerned that it was a  
21     single-center study?

22          **A**     No.

23          **Q**     Do you know how many patients in the  
24     three-year follow-up underwent a physical exam at the  
25     last follow-up?

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1           **A**     A physical exam?

2           **Q**     Yes.

3           **A**     I don't know the exact number.

4           **Q**     Okay. Do you know in the one-year study --

5                   MR. SNELL: You can ask for the study.

6     Jeff, do you have the study you can provide to him,  
7     or do you want us to take a break and find it?

8                   MR. KUNTZ: Take a break and find it, but  
9     he --

10                  MR. SNELL: Look, Jeff. He's got literally  
11     hundreds of pages and all kinds of stuff over here.

12                  MR. KUNTZ: That's great, but he just  
13     brought up the study on his own for support of his  
14     opinion. So I'm asking him about it, and he doesn't  
15     know the answer to them.

16           **Q**     (By Mr. Kuntz) So as we --

17                   MR. SNELL: He said he's looked --

18                   (By Mr. Kuntz) -- sit here right now --

19                   MR. SNELL: -- at hundreds of papers.

20                   (All speaking simultaneously, and reporter  
21     requested clarification.)

22                  MR. SNELL: You asked him to look at a  
23     specific data point. I mean, we will find the study  
24     and --

25                  MR. KUNTZ: He brought up the study on his

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1 own as support, and I asked him basic questions about  
2 them, and he doesn't know about them. So if --

3 MR. SNELL: That's a mischaracterization.

4 MR. KUNTZ: -- you want to go get them and  
5 show them to him, go for it.

6 MR. SNELL: Let's take a break so he can  
7 get the papers out -- the articles.

8 MR. KEITH: All right. Let's go off the  
9 record.

10 (Recess from 5:45 p.m. to 6:08 p.m.)

11 MR. KUNTZ: Okay. We're back on the  
12 record?

13 MR. KEITH: Yes.

14 MR. KUNTZ: Let me find my note. Hold on  
15 one second. Are you guys ready?

16 MR. KEITH: Yeah.

17 Q (By Mr. Kuntz) Dr. Flynn, we were talking  
18 about the de Leval study.

19 A Yes.

20 Q Have you ever reviewed any documents from  
21 Ethicon related to deficiencies in Dr. de Leval's  
22 study?

23 MR. SNELL: Form, vague, "deficiencies."

24 A No, I have not.

25 Q (By Mr. Kuntz) Did you review his study

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1 over the break?

2       **A**     I located the study. I've reviewed it  
3 previous. I just couldn't locate it. Now I've  
4 located the one-year and the three-year data.

5       **Q**     Do you know how many patients in that study  
6 -- well, strike that.

7             You would agree with me that that wasn't  
8 the exact Abbrevio product that was studied in that  
9 series, correct?

10            MR. SNELL: Form, vague.

11       **A**     Are you speaking to the one-year data or  
12 the three-year data?

13            MR. KUNTZ: One-year data.

14       **A**     One-year data. I'm aware that this study  
15 evaluates the original procedure versus the modified  
16 procedure.

17       **Q**     (By Mr. Kuntz) Do you know what the  
18 modified procedure is that was used in that case?

19       **A**     It was a shortened tape. The first  
20 modification related to the shortening of the tape to  
21 12 centimeters. This was carried out directly in the  
22 operating room. The suture loop was added to it.  
23 That was another modification.

24       **Q**     Do you believe the modified product used in  
25 this one-year study is the same product that was

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1 eventually sold as the Abbrevio?

2 **A** I believe it represents the same product.

3 **Q** Is it the exact same product?

4 MR. SNELL: Form, asked and answered.

5 **A** I believe it represents it. I believe that  
6 the study was well done.

7 **Q** (By Mr. Kuntz) Do you believe there was a  
8 washout curve in this study?

9 **A** I'm not certain what you mean by "washout."

10 **Q** Have you reviewed any documents discussing  
11 a washout curve related to de Leval's expertise in  
12 this study?

13 (Pause.)

14 **A** I don't see the word "washout" used in the  
15 article. I'm going through it right now.

16 **Q** Do you recall reviewing any internal  
17 Ethicon documents about a washout curve related to  
18 this study?

19 **A** No.

20 **Q** Do you know how many of the modified  
21 products use laser-cut mesh versus mechanical-cut  
22 mesh?

23 **A** Well, I believe I said earlier that I  
24 thought that all of them were laser-cut. And over  
25 the break, I did look at some data to say that it may

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1 have been half and half.

2 Q Okay. And were you shown that data by  
3 Mr. Snell?

4 A No. I remember reading that in  
5 Dr. Rosenzweig's deposition. And so I looked at  
6 Dr. Rosenzweig's deposition, and he's referring to, I  
7 believe, an internal Ethicon e-mail where they made  
8 reference about it being 50/50.

9 Q But prior to reading plaintiff's expert  
10 deposition on the break, you did not know that half  
11 the products were mechanical-cut mesh that were used  
12 in that study for the modified product?

13 MR. SNELL: Objection. It misstates.

14 A I wasn't aware of it until I read the  
15 deposition. I don't think it states in this de Leval  
16 article.

17 Q (By Mr. Kuntz) Okay. So without the  
18 benefit of Dr. Rosenzweig's deposition or any  
19 internal documents from Ethicon, a physician out in  
20 the public who found this article would have no idea  
21 that half of the products used in the modified  
22 products were mechanical-cut mesh, would they?

23 MR. SNELL: Objection, form. It misstates,  
24 foundation.

25 A Yeah.

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1           **Q**       (By Mr. Kuntz) Do you understand the  
2 question, Doctor?

3           **A**       Yeah, I do. I would say if they just  
4 looked at this article alone, the article doesn't  
5 state that, but there's a lot of other ways that they  
6 could have been made aware of the --

7           **Q**       Like --

8           **A**       -- the laser-cut.

9           **Q**       You tell me one way a doctor reading that  
10 study would know that half the products were  
11 mechanical-cut mesh.

12          **A**       Well, I wasn't speaking specific to the  
13 article. I was speaking to the product in general  
14 and their awareness before using the product.

15          **Q**       Would you be surprised if Dr. Luu testified  
16 that he did not know anything about laser-cut mesh  
17 prior to the time he implanted Mrs. Perry?

18          **A**       Yes.

19                   MR. SNELL: Form, vague. Go ahead.

20          **A**       I would be surprised. Dr. Luu went to the  
21 cadaver lab. Dr. Grier attended the lab. There were  
22 other preceptors there. I think there was  
23 opportunity for that discussion to happen.

24          **Q**       (By Mr. Kuntz) You've testified earlier  
25 there's a thousand studies to support this product,

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1 the TVT Abbrevio. Is that true?

2 **A** I was speaking about the family of TVT  
3 products.

4 **Q** Okay. But you would agree there's not a  
5 thousand studies to support the TVT Abbrevio?

6 MR. SNELL: Form. It misstates.

7 **A** I'm not going to agree to that statement.

8 **Q** (By Mr. Kuntz) How many of those thousand  
9 studies use laser-cut mesh that's used in the  
10 Abbrevio? Have you ever done that analysis?

11 **A** Yeah, I have, and I believe if you just  
12 break down the literature, you know, by five-year  
13 periods, it'd probably match the transition from  
14 mechanical-cut to laser-cut.

15 So all literature involving products before  
16 '06 would involve mechanical. After '06, it would be  
17 more preferential towards laser. So I would think it  
18 would be half and half.

19 **Q** Doctor, you're guessing about that.  
20 Nowhere in any of those studies after 2006 does it  
21 say whether laser-cut or mechanical-cut mesh is used,  
22 correct?

23 MR. SNELL: Form and foundation too.

24 **A** I think it mentions specifically, at least  
25 for the brand of products after their investigation,

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1 once it's an aftermarket study -- if you know what  
2 the product is aftermarket, that's disclosed, and  
3 that's something that you could be aware of.

4 Q (By Mr. Kuntz) Doctor, have you ever been  
5 told by Ethicon or seen any documents what percentage  
6 of products being used in the U.S. are mechanical-cut  
7 versus laser-cut mesh?

8 A I could speak of 2014, and I would say  
9 virtually all mid-urethral slings involving the  
10 Ethicon product line, Boston Scientific product line,  
11 and any of the popular products involve laser-cut  
12 mesh. That's what I can state.

13 Q Do you have any idea percentage-wise how  
14 many -- or what percentage of TVT Obturator products  
15 sold in the United States use laser-cut mesh versus  
16 mechanical-cut mesh?

17 A In 2014?

18 Q Yes.

19 A I don't use the TVT Obturator product right  
20 now, so I don't know the exact number, but I would  
21 think that it would be -- the majority would be  
22 laser-cut.

23 Q Okay. And what about in 2013?

24 A Similar answer. I would say after -- in  
25 2011, most of the products were laser-cut.

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1           **Q**     And I want to ask you -- in all the studies  
2     that you're talking about after 2007, is there  
3     anywhere in any of those studies where it says  
4     "laser-cut mesh is used versus mechanical-cut mesh"?

5           **A**     I think the products are identified in the  
6     aftermarket studies. And so if you're familiar with  
7     the product, you would be familiar with how it's cut.

8           **Q**     But for example, if we're looking at a  
9     study that talks about TVT-O in, say, 2009, you know  
10    Ethicon was using both mechanical-cut mesh and  
11    laser-cut mesh at that time, correct, in the TVT-O?

12          **A**     That was probably the transition period.

13          **Q**     And none of those studies distinguish  
14    whether the TVT-O they were using in the study or  
15    comparing to another product are laser-cut TVT-Os or  
16    mechanical-cut TVT-Os, do they?

17               MR. SNELL: Objection, foundation.

18          **A**     I believe we've been through this quite a  
19    bit, but I believe that the laser-cut mesh is being  
20    used commonly in 2014. There was a transition period  
21    that we mentioned, and then before 2006, it was  
22    mechanical-cut.

23          **Q**     (By Mr. Kuntz) Okay. So what year do you  
24    think that all the products started becoming  
25    laser-cut mesh?

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1 MR. SNELL: Form. It misstates.

2 A TVT Abbrevio has always been laser-cut. TVT  
3 Exact, laser-cut. The Retropubic product, there were  
4 options for that, similar to the Obturator. TVT  
5 Secur I also believe was always laser-cut.

6 So those are statements that I'm confident  
7 in.

8 Q (By Mr. Kuntz) Okay. I guess we're not  
9 seeing eye to eye here.

10 How would I know if I went and looked at a  
11 TVT-O study -- say it was comparing TVT-O to TVT  
12 Retropubic in 2009. How would I know whether the  
13 product that they were using in TVT-O was laser-cut  
14 or mechanical-cut mesh?

15 A I don't know the answer to that.

16 Q There's no way to tell, is there?

17 MR. SNELL: Form.

18 A There's ways of telling. You can discuss  
19 the article with a Ethicon representative. If you  
20 know the authors, you can speak to them. If it lists  
21 the years that the meshes were implanted, you can get  
22 a general idea. Some of the things we've been  
23 talking about, but --

24 Q (By Mr. Kuntz) But that's not -- okay.

25 Doctor, they are still using mechanical-cut

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1 mesh and laser-cut mesh in the TVT-O today. Did you  
2 know that?

3 **A** No. I'm not using the TVT-O products. So  
4 I'm not as well studied on that currently.

5 **Q** Okay. Do you have any idea how many TVT-O  
6 laser-cut meshes were sold in 2008 versus TVT-O  
7 mechanical-cut mesh?

8 **A** I don't know the numbers, no.

9 **Q** Have you ever looked at any sales numbers  
10 comparing the sales of TVT-O mechanical-cut mesh  
11 versus TVT-O laser-cut mesh for any years from 2007  
12 to 2014?

13 **A** I've never reviewed the sales numbers for  
14 any of these products.

15 **Q** Okay. So if I'm a doctor and I go pull a  
16 study and it's comparing a product against TVT-O,  
17 there's no way for me to know whether it's  
18 mechanical-cut or laser-cut being used in the TVT-O  
19 unless I ask Ethicon, correct?

20 **MR. SNELL:** Form and foundation, asked and  
21 answered.

22 **A** There's other sources beyond Ethicon. The  
23 authors I had mentioned, and then, you know, there's  
24 certain products that were exclusively offered as  
25 laser-cut like Abbrevio.

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1           So there's things that you can infer. You  
2   can look at -- if you go to the cadaver lab, if you  
3   attended prof ed events, if you spoke with Ethicon,  
4   yes. So there's multiple sources.

5           **Q**     (By Mr. Kuntz) Do you agree that the only  
6   other TVT devices Ethicon has sold that has a mesh  
7   length of less than 45 centimeters is no longer on  
8   the market?

9           MR. SNELL: Objection, form.

10          **A**     I don't think I can possibly be familiar  
11   with all the products Ethicon has ever offered, but I  
12   know they have 45-centimeter mesh and they have a  
13   12-centimeter mesh.

14          **Q**     (By Mr. Kuntz) Do you believe that the  
15   Abbrevio is safe and effective for the treatment of  
16   stress urinary incontinence in overweight and obese  
17   women?

18          **A**     I believe obesity is a risk factor for  
19   surgery in general, but certainly the product can be  
20   used in that population.

21          **Q**     Correct. And you implant the TVT Abbrevio  
22   in obese women, correct?

23          **A**     I have.

24          **Q**     And there's no contraindication not to use  
25   the TVT Abbrevio in obese women, correct?

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1           **A**     Correct.

2           **Q**     Do you have an opinion whether the Prolene  
3 mesh used in the TVT Abbrevio degrades?

4           **A**     I do.

5           **Q**     What is that opinion?

6           **A**     That I don't believe it -- I don't believe  
7 it degrades. I don't see that --

8           **Q**     How do you -- how do you define  
9 "degradation"?

10          **A**     How do I define it?

11          **Q**     Yes.

12          **A**     That would be gross visual deterioration of  
13 the product, a broken product, you know, inside the  
14 patient.

15          **Q**     So if you went in to remove a mesh and you  
16 saw it as broken or brittle or falling apart, you  
17 would define that as degradation?

18          **A**     I said broken. I didn't say brittle. I  
19 said broken.

20          **Q**     Okay. And what do you mean by "broken"?

21          **A**     The mesh no longer in one piece, separated.

22          **Q**     Okay. Have you ever seen any degraded mesh  
23 in any of your explant or revision surgeries?

24          **A**     It's not something I've seen on any of my  
25 explantation surgeries.

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1           **Q**     Do you have any background in polymer  
2 chemistry?

3           **A**     I have as much as any other physician in my  
4 position, but I'm not a chemist.

5           **Q**     Are you -- have you done any bench research  
6 on polypropylene?

7           **A**     No.

8           **Q**     Have you done any lab research on  
9 polypropylene?

10          **A**     No.

11          **Q**     Never published any opinions that  
12 polypropylene does not degrade in the human body?

13          **A**     That's not a comment I've made  
14 specifically.

15          **Q**     Have you ever looked at any of the mesh  
16 you've explanted under a microscope?

17          **A**     Yes.

18          **Q**     And none of the mesh that you've looked at  
19 under the microscope has shown what you call  
20 degradation?

21          **A**     I don't look under SEM. We're just looking  
22 under standard microscopes on H&E preparations. So  
23 it's just a standard preparation that any hospital  
24 would use when sending a specimen for gross or  
25 microscopic analysis.

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1           **Q**     Have you ever reviewed any SEM photos of  
2     explants that showed degradation?

3           **A**     I'm aware of an article in the literature  
4     that shows SEM photos, but I've never prepared any  
5     SEM photos of any explants that I've been involved  
6     in.

7           **Q**     What article?

8           **A**     Well, there's the Clave article, and I  
9     think his articles are referenced by a number of  
10    other authors.

11          **Q**     Any other articles that you've read on  
12    degradation besides Clave?

13          **A**     Well, there's the Costello case report.  
14    There's other articles looking at degradation of  
15    biological graphs. There's the Patel article. I  
16    believe Ostergard is involved in that article. I've  
17    read editorials authored in rebuttal to the Clave  
18    article.

19          **Q**     Anything else?

20          **A**     Just to repeat that, the Goldman rebuttal,  
21    the Clave article, the Costello article.

22          **Q**     Have you ever reviewed any internal Ethicon  
23    documents that discuss degradation in the Prolene  
24    mesh?

25          **A**     No, I have not.

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1           **Q**     Have you ever reviewed any internal test  
2 performed by Ethicon on its Prolene search -- sutures  
3 that discussed degradation?

4           **A**     Can you repeat the question?

5           **Q**     Have you ever reviewed any internal test  
6 performed by Ethicon on its Prolene sutures that  
7 discussed degradation?

8           **A**     I'm not aware of that. I know that --

9                   MR. SNELL: Jeff, I don't think that  
10 Guelcher's exhibits have been finalized by the court  
11 reporter. So whenever they are, we will get them to  
12 him, but I don't think he's had those yet.

13                  MR. KUNTZ: Well, I'm not talking about  
14 Guelcher's exhibits, Burt. I'm talking about many  
15 other documents that have been around way before  
16 Guelcher was involved in this litigation.

17           **Q**     (By Mr. Kuntz) So my question is: Have  
18 you reviewed any internal studies from Ethicon that  
19 discuss degradation? Simple question.

20           **A**     My quick answer is no.

21           **Q**     Okay. Do you know what the TVT Abbrevio IFU  
22 says about degradation?

23           **A**     I don't believe it comments on degradation.

24           **Q**     Okay.

25                   MR. SNELL: Do you have a copy of the IFU

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1 that you can bring out?

2 Q (By Mr. Kuntz) Well, Doctor, you reviewed  
3 the IFU in preparation for your deposition, correct?

4 A Correct.

5 Q You've used it many times and looked at it  
6 before using the Abbrevio product, correct?

7 A Correct.

8 Q And you have no idea, as you sit here  
9 today, what the IFU Abbrevio says about degradation,  
10 correct?

11 A Let me just pause while I get the IFU out.

12 Q Look at the bottom of Page 8 of the IFU.  
13 (Discussion off the record.)

14 MR. KEITH: He's looking for it, Jeff.

15 MR. KUNTZ: It's in our folder, the first  
16 folder, Sean.

17 MR. KEITH: All right. Do you got it?  
18 What exhibit is that notebook that you're looking at?  
19 Exhibit 15. Jeff, what did you tell him -- he's got  
20 the IFU. Where did you tell him to look?

21 MR. KUNTZ: Bottom of Page 8.

22 A Okay. Under the section Adverse Reactions?

23 Q (By Mr. Kuntz) Under the section Actions,  
24 the last sentence.

25 A "The material's not absorbed, nor is it

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1 subject to degradation or weakening by the action of  
2 tissue enzymes."

3 Q You agree that the Ethicon TVT IFU --  
4 Abbrevio IFU says that the mesh is not subject to  
5 degradation?

6 MR. SNELL: Objection, form, foundation.  
7 The document speaks for itself. Incomplete  
8 statement.

9 Q (By Mr. Kuntz) Did you know that before  
10 today, Doctor?

11 A I knew before today that the whole family  
12 of TVT products do not degrade. Yes, I knew that  
13 before today.

14 Q Okay. And what do you base that opinion  
15 on?

16 A That's based on over 10 years of implanting  
17 Type I polypropylene mesh from a variety of  
18 manufacturers. I've been in one practice in one town  
19 for my entire professional career outside of  
20 residency and fellowship.

21 I have patients that I followed in my own  
22 personal practice for as long as I've been in  
23 practice. So I feel that --

24 Q Have you ever had to look for any research  
25 that talks about degradation of polypropylene meshes

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1 and the clinical significance related to the  
2 degradation?

3 **A** I'm constantly reviewing the literature,  
4 and I'm on alert, always looking for new things that  
5 might become knowledgeable to me. Things -- new  
6 discoveries.

7 So yeah, I have a scientifically  
8 inquisitive mind, and I read the literature, and if  
9 there's something new, then I'm going to look at  
10 that.

11 **Q** Okay. Have you been provided by Ethicon  
12 any articles or abstracts that suggests that  
13 degradation occurs with these meshes and causes  
14 clinical complications? Have you ever seen any  
15 articles in those regards?

16 **A** That have been provided to me by Ethicon?  
17 Well, if you're speaking to the Clave article, I was  
18 aware of that before --

19 **Q** I'm not talking about Clave.

20 **A** Okay.

21 **Q** Let me ask you this --

22 **A** Sure.

23 **Q** -- from either Ethicon or your own  
24 research, have you ever seen any articles that talk  
25 about degradation of meshes and clinical

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1 complications therefrom?

2 MR. SNELL: Objection, form, overbroad,  
3 vague as to which mesh.

4 A Yeah, I -- I'm aware of some ex vivo  
5 studies that discuss mesh that have been explanted  
6 and then pristine pieces of mesh that have never been  
7 implanted, but I'm not aware of any clinical  
8 correlations in those papers.

9 Q (By Mr. Kuntz) Okay. So you have never  
10 seen any papers that talk about a clinical  
11 correlation between degradation?

12 A Not provided to me by Ethicon. You may be  
13 speaking to the Patel paper -- if you'd like, we can  
14 look at that -- and some of the opinions and the  
15 rebuttals to those hypotheses, but they're not  
16 clinical studies.

17 If you're talking about clinical studies,  
18 you're talking about Type I -- or Level I data,  
19 certainly there's no studies of that level of  
20 evidence.

21 Q So do you only rely on Type I-level  
22 evidence when you're determining what product to use?

23 A I prioritize the evidence that's important.  
24 So if there is Type I evidence -- Level I evidence --  
25 excuse me -- Level I evidence, I'm going to look at

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1 that more strongly, but if there's no Level I or II  
2 and it's a problem -- that I have patients that have  
3 that problem and need treatment, I'll go to the  
4 highest level of evidence that I can find.

5 Q Right. You'd agree that de Leval's one-  
6 and three-year study on the modified -- what became  
7 the Abbrevio is not Level I evidence, correct?

8 MR. SNELL: Objection, foundation.

9 A I'm aware that his three-year study  
10 randomized patients. It wasn't multi-study --  
11 multi-center -- excuse me, but it was a randomized  
12 controlled trial, and it had an adequate number of  
13 patients.

14 The level of evidence in that trial, I  
15 would agree it wasn't Level I.

16 (Reporter requested clarification.)

17 A Was not Level I.

18 Q (By Mr. Kuntz) When we're talking about  
19 the gold standard, who makes the decision as to  
20 whether a product is gold standard or not?

21 A I don't think it's any one -- one person.  
22 It's a consensus amongst professional societies,  
23 amongst community standards.

24 It may vary based on geographic region or  
25 country based on what's available and what's feasible

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1 to that medical community.

2 Q Do you believe that Burch is still the gold  
3 standard for the treatment of stress urinary  
4 incontinence?

5 A I believe it's an effective procedure, but  
6 it's certainly not the most popular procedure, and I  
7 don't believe it's -- I think the gold standard -- I  
8 wouldn't use that word with the word "Burch," but I  
9 think it's an acceptable procedure.

10 Q Do you define "gold standard" as the most  
11 popular procedure?

12 MR. SNELL: Objection, form, asked and  
13 answered.

14 A I think that the gold standard procedure  
15 isn't always the most popular procedure, but it  
16 usually is. But there's oftentimes -- you know, the  
17 word "terminal procedure" is often the most  
18 efficacious procedure, but it might not be a  
19 procedure that's readily performed by a wide variety  
20 of physicians.

21 So gold standard, it's usually the most  
22 popular procedure, but it's not necessarily the most  
23 popular.

24 Q (By Mr. Kuntz) Do you think you have to  
25 have valid RCTs for a product to become the gold

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1 standard?

2           **A**     No. You're only measuring the product  
3 across other procedures within that category. So,  
4 you know, for some diseases and some surgeries, it's  
5 a prevalent enough problem that there would be RCTs  
6 for less common diseases, less common problems, less  
7 complications. There may never be an RCT.

8           **Q**     Okay. So you believe that the  
9 mechanical-cut mesh TVT is the gold standard,  
10 correct?

11          **A**     Mechanical-cut?

12          **Q**     Mesh.

13          **A**     No. I believe Type I macroporous  
14 polypropylene mesh is the most commonly used type of  
15 mid-urethral sling, and I believe the mid-urethral  
16 sling is the gold standard, but I don't differentiate  
17 between laser- and mechanically-cut. It seems very  
18 arbitrary.

19          **Q**     Okay. So you believe any mid-urethral  
20 sling that uses an amid Type I macroporous  
21 classification for its mesh is the gold standard,  
22 right?

23          **A**     I believe that that's appropriate for  
24 mid-urethral slings, and the mid-urethral sling is  
25 the gold standard for stress urinary incontinence.

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1           **Q**     And we're talking about full-length  
2     mid-urethral slings, correct?

3                   MR. SNELL: Objection, form. It misstates.

4           **A**     If we go back to the AUA statement and the  
5     SUFU statement, both transobturator and retrobubic  
6     full-length mid-urethral slings.

7           **Q**     (By Mr. Kuntz) Okay. Is that -- what AUA  
8     statement are you basing it on? The November 2011  
9     one?

10          **A**     Let me go ahead and pull that up. Yeah.  
11     The 2011 American Urologic Position on the Use of  
12     Vaginal Mesh for Surgical Treatment of Stress Urinary  
13     Incontinence. We've marked that as Exhibit 6.

14                   MR. KEITH: It's an article in Exhibit 6.

15          **Q**     (By Mr. Kuntz) Let me ask you this,  
16     Doctor: Do you agree with this statement: The level  
17     of evidence supporting the universal use of any  
18     single SUI surgical procedure for the treatment of  
19     all patients with SUI is poor?

20          **A**     Can you repeat the question?

21          **Q**     The level of evidence supporting the  
22     universal use of any single SUI surgical procedure  
23     for the treatment of all patients with SUI is poor?

24          **A**     No. I would disagree with that.

25          **Q**     Okay. Because you believe mid-urethral

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1 slings are the number one choice and the gold  
2 standard?

3 **A** I believe that, and I believe the  
4 professional societies believe that, and I believe 95  
5 percent of practicing urologists and urogynecologists  
6 believe that.

7 **Q** Okay. Have you ever talked to Dr. Rovner?  
8 Does he believe that?

9 **A** Dr. Rovner? Certainly. He is one of the  
10 authors on the statement for SUFU. He's the  
11 president of -- former president of SUFU. So I  
12 believe he's quite familiar with that.

13 **Q** Okay. Did you ever get a copy of the AUGS  
14 statement when we were on break?

15 **A** I believe we always had the statement.

16 **MR. SNELL:** I think you already covered  
17 that.

18 **MR. KUNTZ:** Well, no, because you wanted  
19 him to see it, Burt.

20 **Q** (By Mr. Kuntz) Let me ask you this about  
21 --

22 **MR. SNELL:** He had it -- he pulled it for  
23 you, I think, or maybe I'm mis --

24 **Q** (By Mr. Kuntz) Just answer this question.  
25 Do you agree or disagree with this statement, Doctor:

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1 The safety and effectiveness of multi-incision slings  
2 --

3 MR. SNELL: Hold on. You've got to --

4 Q (By Mr. Kuntz) -- is well established --  
5 (All speaking simultaneously, and reporter  
6 requested clarification.)

7 MR. KEITH: She can't keep up with you,  
8 Jeff.

9 Q (By Mr. Kuntz) Do you agree with this  
10 statement: The safety and effectiveness of  
11 multi-incision slings is well established in clinical  
12 trials that followed patients for up to one year?

13 A Let me have you repeat that one more time.

14 Q The safety and effectiveness of  
15 multi-incision slings is well established in clinical  
16 trials that followed patients for up to one year.

17 A Yes, I would agree that the efficacy and  
18 safety is well established.

19 Q For only up to one year?

20 A No. Beyond one year, but I think that --  
21 you asked up to one year, yes. If you asked me two  
22 years, I would say yes. Three years, I would say  
23 yes.

24 Q How many years would you say it's been  
25 studied for?

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1           **A**     Well, if you look at the Nilsson paper,  
2     it's been studied for as many as 17 years.

3           **Q**     Have you looked at any of the raw data from  
4     the Nilsson study?

5           **A**     What do you mean by "raw data"?

6           **Q**     Any of the patient-level data.

7                   MR. SNELL:   Form, vague.   Go ahead.

8           **A**     I can get the article out and look at the  
9     article, but I'm not -- I don't have his spreadsheet,  
10    if that's what you're asking me.

11          **Q**     (By Mr. Kuntz)   Do you know how many  
12    patients were in the original cohort for the Nilsson  
13    17-year data?

14          **A**     I know that he did lose an expected  
15    percentage of patients over the 17-year follow-up.   I  
16    think at the end of the follow-up, there might have  
17    been half of the cohort left.

18          **Q**     Okay.

19                   MR. SNELL:   You can get the article and  
20    pull it out and look at it.   So let's not guess.   If  
21    you want to get it, get it.

22          **A**     We're going to go ahead and pull that  
23    article.

24          **Q**     (By Mr. Kuntz)   Well, you -- let me tell  
25    you this -- ask you this:   You would agree that the

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1 Nilsson study did not deal with the laser-cut mesh  
2 placed in the obturator space, correct?

3 **A** Correct. Nilsson study involved TVT  
4 Retropubic, also known as TVT Classic.

5 MR. KEITH: What exhibit is that?

6 THE DEPONENT: This is Exhibit No. 16.

7 MR. SNELL: Do you just want to use that  
8 copy there?

9 THE DEPONENT: Yeah.

10 **A** So it says, "78 percent of potentially  
11 assessable women were evaluated either by clinic  
12 visit or by telephone interview." 78 percent.

13 **Q** (By Mr. Kuntz) So there were no physical  
14 examinations on a good percentage of those women, but  
15 they were interviews over the phone, correct?

16 MR. SNELL: Objection, form, vague, "good  
17 percentage."

18 **A** Of the 58 women who were available, 46  
19 women visited the clinic, 12 were interviewed by  
20 telephone. So the -- you know, the majority -- you  
21 know, more than 75 percent were examined.

22 **Q** (By Mr. Kuntz) Do you know how many  
23 patients were lost at follow-up at the 17-year time  
24 period?

25 **A** 11 women died. So they were lost to

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1 follow-up, I guess. 16 women could not be contacted.  
2 So of the 79 women that were remaining, 16 could not  
3 be contacted. Five women had impaired mental  
4 capacity. So the number went from 90 to 79 to 58  
5 over 17 years.

6 **Q** Do we know why -- do you know why any of  
7 the women died or how they died?

8 **A** I believe they died of natural causes, but  
9 this is not a cancer study. So, you know, I don't  
10 think that's as important. With cancer studies, we  
11 usually look at cancer-free survival versus  
12 disease-free survival.

13 **Q** Doctor, do you believe that the Prolene  
14 mesh and the TVT Abbrevio is lightweight mesh?

15 **A** Like we mentioned earlier, TVT Abbrevio Type  
16 I by the mid-classification macroporous -- you can  
17 use the word "lightweight" if you want.

18 **Q** What's your definition of "lightweight  
19 mesh"?

20 **A** Lightweight mesh, in my mind, would be only  
21 relevant compared to products in its category. So if  
22 you look at the Pam Moalli paper, she studies the  
23 lightweight meshes. That would include TVT mesh.

24 So meshes that are more than 75 microns in  
25 pore size and weigh less than 100 grams per meter

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1 squared.

2           **Q**     So less than 100 grams per meter squared  
3 you consider lightweight?

4           **A**     I would. Let me get the Moalli paper out  
5 just to be certain of that number. And we could  
6 submit that as an exhibit.

7           MR. KEITH: It's probably part of an  
8 exhibit already.

9           **A**     Yeah, it's probably part of the exhibit.

10           MR. KEITH: Is that in the orange folder?

11           THE DEPONENT: No. I don't have it in the  
12 orange folder.

13           MR. SNELL: It might be in this one here  
14 (indicating).

15           MR. KEITH: Jeff, I'm going to go to the  
16 restroom. You can keep going.

17           MR. SNELL: Why don't we take a break.  
18 I've got to use the restroom, too.

19           MR. KEITH: I'm sorry. I didn't want to --

20           MR. SNELL: It's okay.

21           THE DEPONENT: No, that's all right.

22           MR. KUNTZ: We're not taking a -- can we  
23 wait until after this line of questioning?

24           MR. SNELL: Yeah, that's fine. Go ahead.

25           **Q**     (By Mr. Kuntz) What do you define --

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1 MR. SNELL: Hold on. He's looking for the  
2 Moalli paper.

3 Q (By Mr. Kuntz) Let me ask you this: Is  
4 the Moalli paper your sole basis of the definition of  
5 what lightweight mesh is, Doctor?

6 A No. It's one of many criteria or papers I  
7 use.

8 Q What are the other papers --

9 A I like to look at the Dietz paper, and then  
10 --

11 Q -- for definitions --

12 (All speaking simultaneously, and reporter  
13 requested clarification.)

14 Q (By Mr. Kuntz) -- for definitions of mesh?

15 A I think for characterization of the meshes  
16 in terms of pore size, stiffness, breaking strengths,  
17 all those things are important factors that one  
18 consider.

19 Q What Moalli paper are you looking at?

20 A We're looking from Exhibit No. 16.

21 Q What's the year on it?

22 A The year is 2008. International  
23 Urogynecology Journal, 2008, Pamela Moalli.

24 Q Have you read any other of Pam Moalli's  
25 newer articles? Are those on your reliance list?

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1           **A**       Yeah. I've looked at her recent article  
2       looking at carcinogenesis -- or I should say the lack  
3       of -- with respect to polypropylene mesh.

4           **Q**       What do you define as a medium-weight mesh?

5                   MR. SNELL: Form, vague as to application.

6           **A**       I don't have a definition for that. It's  
7       not a term I use.

8           **Q**       (By Mr. Kuntz) Okay. So you've never seen  
9       Ethicon use that term?

10                  MR. SNELL: Objection, form, vague as to  
11       application.

12           **Q**       (By Mr. Kuntz) What do you define as a  
13       heavyweight mesh, Doctor?

14                  MR. SNELL: Objection, form, vague as to  
15       application, asked and answered.

16           **Q**       (By Mr. Kuntz) What do you consider a  
17       heavyweight mesh used for stress urinary  
18       incontinence?

19           **A**       I don't believe there are any on the  
20       market. There's some historic meshes that we can  
21       speak to.

22           **Q**       What's the heaviest weight you know of in a  
23       mesh used for SUI treatment?

24           **A**       Historically or currently?

25           **Q**       Let's start with historically.

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1           **A**       Well, historically, I know that products  
2       such as Gore-Tex, Mersilene, or heavier-weight  
3       meshes. So many of the Type II, Type III, Type IV  
4       meshes from the amid classification I would consider  
5       heavyweight meshes.

6           **Q**       Okay. Anything else? What about Marlex?

7           **A**       Yeah. Marlex would be a mesh that I'm not  
8       as familiar with. I know it was a polypropylene  
9       mesh, but I believe the pore size on that mesh and  
10      the size of the fibers, specifically the mils were  
11      thicker than -- than on polypropylene or Prolene mesh  
12      or Gynecare TVT mesh.

13          **Q**       Doctor, I'm talking about two different  
14      things. I'm not talking about pore size. I'm  
15      talking about weight right now. Do you understand  
16      that?

17          **A**       I do.

18                   MR. SNELL: Objection, form. Go ahead.

19          **A**       But I think when you're going to ask me to  
20      classify lightweight, heavyweight, mid-weight -- I  
21      don't look just at the weight. I look at the mil  
22      fiber; I look at the pore size; I look at the mesh  
23      thickness, the porosity.

24                   I believe most people when they speak of  
25      light- and heavyweight meshes, they're referring to a

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1 lot more than just the weight.

2 Q (By Mr. Kuntz) Well, you said lightweight  
3 mesh is less than 100 grams. That's a weight  
4 measurement, correct?

5 A I said it's right around 100 grams. So,  
6 you know, 100 grams to me is a lightweight mesh.

7 Q What about -- what is a heavyweight mesh?

8 A A heavyweight mesh? I think that you would  
9 probably be looking at something that's microporous.

10 Q What about weight? I'm not talking about  
11 pore size, Doctor.

12 MR. SNELL: Objection, form. He's  
13 testified as to how he considers it.

14 Q (By Mr. Kuntz) What is -- do you have any  
15 idea what the literature calls heavyweight,  
16 lightweight, or medium-weight, Doctor?

17 MR. SNELL: Objection, form, vague as to  
18 application.

19 Q (By Mr. Kuntz) What does Pam Moalli call a  
20 heavyweight mess? How many grams?

21 MR. SNELL: Same objection, vague as to  
22 application.

23 Q (By Mr. Kuntz) Let me ask you this,  
24 Doctor: Do you think that the weight of mesh change  
25 when it's used in one place of the body versus the

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1 other? Is that your opinion?

2 **A** I think that the weight of the meshes are  
3 only relevant to the body part they're used in and  
4 when compared to products in that category.

5 So lightweight, heavyweight might have  
6 different criteria for hernia than it does for SUI  
7 than it does for POP.

8 **Q** Okay. So a mesh could be lightweight --  
9 strike that.

10 A mesh could be heavyweight for hernia use  
11 but lightweight for stress urinary incontinence use  
12 or for a POP mesh. Is that what you're saying?

13 **A** Absolutely. Someone who is considered  
14 heavy in one part of the country might be considered  
15 thin in another part.

16 **Q** What are you talking about? Are you  
17 talking about other parts of the country or the body?

18 **A** Other parts of the country, other parts of  
19 the world. So I think it's all relative in the eyes  
20 of the beholder.

21 **Q** Do you believe that a mesh can be  
22 heavyweight for a hernia mesh but then if that same  
23 mesh is used for stress urinary incontinence, it can  
24 be a different weight?

25 MR. SNELL: Objection, form, asked and

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1 answered.

2           **A**       The weight stays the same. How we  
3 characterize it and how we describe it and  
4 characterize it is what's different.

5                   So to give an example of mesh that is  
6 considered heavyweight for prolapse would probably be  
7 considered lightweight for hernia. Hernia meshes in  
8 general are going to be much heavier. The mil fibers  
9 are larger. The pore sizes are different. The mesh  
10 overall size surface area is going to be much larger.

11                  So, you know, it's hard to compare across  
12 those three processes: hernia, POP, and SUI. So the  
13 weight doesn't change, but how we characterize it  
14 does.

15           **Q**       (By Mr. Kuntz) Do you believe that mesh in  
16 the abdomen acts the same way as mesh in the pelvic  
17 floor?

18                   MR. SNELL: Form, vague, "acts."

19           **A**       Yeah. Can you be more specific on "acts"?

20           **Q**       (By Mr. Kuntz) Have you ever seen any  
21 Ethicon documents discussing how mesh acts or reacts  
22 in the abdomen as it's compared to the pelvic floor?  
23 Is it the same?

24                   MR. SNELL: Objection, form, compound.

25           **A**       Yeah. Again, I'm not going to answer that

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1 with the word "same." You'd have to give me examples  
2 in terms of how the body reacts or how -- the forces  
3 that are applied to the mesh.

4 Q (By Mr. Kuntz) You can't answer that  
5 question?

6 A No, I can't answer that question, not --

7 Q Have you ever seen --

8 A -- the way you asked it.

9 (All speaking simultaneously, and reporter  
10 requested clarification.)

11 Q (By Mr. Kuntz) Have you ever seen any  
12 discussion about that issue in any Ethicon internal  
13 documents?

14 MR. SNELL: Objection, form, vague, "that  
15 issue." It relates back to the previous objection.

16 A Yeah. I mean, that's -- you're asking me  
17 to speculate there, and I'm not going to do that.

18 Q (By Mr. Kuntz) So you haven't seen any  
19 documents that discuss that issue, right, Doctor?

20 MR. SNELL: Same objection, "that issue,"  
21 vague. It relates back to the previous objection.

22 A All of the professional educational  
23 materials that have been provided to me, comments I  
24 made at meetings, slide shows that I presented, all  
25 understanding that I've ever had with mid-urethral

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1 tapes across various manufacturers, Obturator,  
2 Retropubic, full-length or mini, they're all  
3 lightweight.

4 I've never used anything but a lightweight  
5 mesh for SUI. That's all anybody has ever used for  
6 the last 15 years.

7 **Q** (By Mr. Kuntz) Okay. Have --

8 **A** Heavyweight mesh -- you're bringing up --  
9 (All speaking simultaneously.)

10 **A** You are bringing up a conversation from the  
11 1980s.

12 **Q** (By Mr. Kuntz) Have you ever reviewed any  
13 Ethicon internal documents that calls the Prolene  
14 mesh used in the TVT line of products heavyweight?

15 **A** No.

16 **Q** Have you ever reviewed any literature that  
17 calls the Prolene mesh in the TVT line of products  
18 heavyweight?

19 MR. SNELL: Objection, form, vague.

20 **A** Can you repeat the question?

21 **Q** (By Mr. Kuntz) Have you ever reviewed any  
22 literature that calls the Prolene mesh in the TVT  
23 line of products heavyweight?

24 **A** I'm sure Dr. Ostergard and others like him  
25 -- experts that you guys use have called it

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1     heavyweight, but I don't think that in any of the  
2     Ethicon material and in any of the RCTs has the mesh  
3     ever been called heavyweight.

4           **Q**     You agree that lightweight mesh is better  
5     than heavyweight mesh for SUI slings, correct?

6           MR. SNELL:  Objection, form, vague.

7           **A**     Incorrect.

8           **Q**     (By Mr. Kuntz)  Explain why you think that  
9     a heavyweight mesh could be better than a lightweight  
10    mesh for SUI treatment.

11          MR. SNELL:  Objection.  It misstates  
12    testimony opinion.

13          **A**     What I mentioned earlier in the deposition,  
14    what I'll mention again now is that there's an  
15    optimal pore size, there's an optimal weight, there's  
16    an optimal stiffness, and it's a matter of finding  
17    the right balance.

18                 And so extremes in either direction are not  
19    going to be optimal.  You want to find a balance.  So  
20    if the mesh is too lightweight, it's going to not  
21    provide enough support to the urethra; it's going to  
22    be completely infective.

23                 So, you know, there's an extreme to how  
24    light you can make a mesh, and if it's too light,  
25    it's not going to be effective.  So I think that the

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1 mesh characteristics of the Gynecare TVT are ideal.

2 Q (By Mr. Kuntz) Do you agree that there  
3 should not be any heavyweight meshes for SUI sling  
4 products on the market today?

5 MR. SNELL: Form, foundation, vague.

6 A Can you repeat the question?

7 Q (By Mr. Kuntz) Do you agree that there  
8 should be no heavyweight meshes in SUI slings on the  
9 market today?

10 MR. SNELL: Objection, form, vague,  
11 foundation.

12 A You'd have to give me a number on what you  
13 consider heavyweight, but the heavyweight meshes I'm  
14 aware of that have been used historically haven't  
15 been used since the 1980s, early 1990s.

16 Q (By Mr. Kuntz) Did you tell me what your  
17 definition of "heavyweight mesh" is? How many grams?

18 MR. SNELL: Objection, form, asked and  
19 answered.

20 MR. KUNTZ: I don't think he's ever  
21 answered it.

22 MR. SNELL: He told you he looks at beyond  
23 just the number. He's told you that three times, I  
24 think.

25 A If you want an answer, I've defined

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1     lightweight, and Gynecare TVT is lightweight. Pore  
2     size greater than 75 microns. In fact, the pore size  
3     is over 1,300 microns, and the weight is 100 grams,  
4     which is nearly the same weight of any other products  
5     in its category.

6             It's the same weight as the Boston  
7     Scientific mesh that Dr. Luu is using today.

8             **Q**     (By Mr. Kuntz) What's your basis for  
9     believing that the TVT Abbrevio mesh is lightweight?

10            MR. SNELL: Objection, form, asked and  
11     answered.

12            **A**     The basis is from information provided to  
13     me from Ethicon, review of the scientific literature,  
14     including the Moalli paper, review of meshes from  
15     other products like Boston Scientific Obtryx II,  
16     transobturator mid-urethral sling, which we have  
17     here as an exhibit. So it's certainly in the same  
18     category as that mesh.

19            So if you're going to call one heavyweight  
20     or one lightweight, those two meshes are married to  
21     each other.

22            The AUGS/SUFU 2014 position statements -- I  
23     can go on and on, but I think any reasonable surgeon  
24     would consider Gynecare TVT Type I mesh to be  
25     lightweight.

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1           **Q**       (By Mr. Kuntz) And, again, you -- you've  
2 never seen any internal documents from Ethicon that  
3 call the TVT Prolene mesh heavyweight, correct?

4           MR. SNELL: Objection, form and foundation.

5           **A**       Yeah. I haven't seen any internal  
6 documents, but, again, I'm not aware of a lot of  
7 these internal documents.

8                   I don't work for Ethicon. You know, I'm  
9 aware of the scientific literature and the prof  
10 education that they provide me.

11          **Q**       (By Mr. Kuntz) Doctor, you do work for  
12 Ethicon. You have been consulted with them -- you  
13 consulted with them for seven years. So that's not  
14 true.

15                   My question is real simple. You have  
16 binders and binders and binders of documents there,  
17 and you've been preparing for this depo for six  
18 months.

19                   Have you ever been given or reviewed any  
20 documents internally from Ethicon that call the TVT  
21 Prolene mesh heavyweight?

22           MR. SNELL: Objection. I'm going to move  
23 to strike the attorney comment in the preceding --  
24 leading up to the preceding question, and objection  
25 as asked and answered on the question. Form. Asked

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1 and answered about three times. Go ahead.

2 **A** I'm satisfied with my answers at this  
3 point. I'm not going to spend any more time on that.

4 **Q** (By Mr. Kuntz) Would it surprise you if  
5 Ethicon had internal documents that called the TVT  
6 Prolene mesh heavyweight?

7 **A** You know, Ethicon is a corporation. If you  
8 want to speak to one person, there might be some  
9 person who is less informed than others that may have  
10 made that comment somewhere internally during a  
11 private communication, but that's not something that  
12 was taught. That's not something that's in any of  
13 the published literature or literature they share  
14 with their physicians.

15 So it's an overly broad statement. There  
16 might be some employee somewhere -- some new sales  
17 rep that may have mischaracterized the mesh.

18 **Q** Okay. Doctor, do you agree that physicians  
19 should be made aware of all the significant safety  
20 risks associated with the product in the IFU?

21 MR. SNELL: Objection, form, vague.

22 **A** It should be made aware by whom?

23 **Q** (By Mr. Kuntz) By Ethicon in the IFU. Do  
24 you agree that physicians should be made aware of all  
25 the significant safety risks associated with the

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1 product in the IFU?

2 MR. SNELL: Objection, form and foundation,  
3 vague, "all safety."

4 A I believe that the physician has a personal  
5 responsibility to read the IFU, and I believe that  
6 most of their awareness of risk and benefits of  
7 surgery come from their medical school, residency,  
8 fellowship, training, and clinical practice.

9 MR. KUNTZ: Okay. That's not the answer to  
10 my question. I'll move to strike.

11 Q (By Mr. Kuntz) Do you agree or disagree  
12 physicians should be made aware of all the  
13 significant safety risks associated with the product  
14 in the IFU?

15 MR. SNELL: Objection, form, asked and  
16 answered.

17 Q (By Mr. Kuntz) Do you agree or disagree?

18 A I disagree.

19 Q Okay. Do you agree or disagree that a  
20 manufacturer of a medical device that will be  
21 implanted in a woman's body is required to disclose  
22 all significant risks to doctors that come with the  
23 use of the device?

24 MR. SNELL: Objection, form, calls for a  
25 legal conclusion.

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1           **A**       I would disagree.

2           **Q**       (By Mr. Kuntz) Do you agree or disagree?

3       The Warnings and Adverse Reaction section should  
4       include all significant risks and complications  
5       related to the use of the TVT.

6           MR. SNELL: Objection, form, calls for a  
7       legal conclusion, vague.

8           **A**       I'm going to disagree.

9           **Q**       (By Mr. Kuntz) Do you agree or disagree  
10       that an IFU should never exclude known hazards or  
11       complications?

12          MR. SNELL: Objection, form, vague.

13          **A**       I would disagree.

14          **Q**       (By Mr. Kuntz) Do you agree that it would  
15       be reasonable for physicians to know that the mesh in  
16       the TVT product has been tested multiple times to be  
17       severely or marked cytotoxic?

18          MR. SNELL: Objection, form and foundation,  
19       lacks foundation, calls for a legal conclusion, calls  
20       for speculation. Go ahead.

21          **A**       Can you repeat the question?

22          **Q**       (By Mr. Kuntz) Agree that it would be  
23       reasonable for physicians to know that the mesh in  
24       the TVT product has been tested multiple times to be  
25       severely or marked cytotoxic?

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1 MR. SNELL: Same objections, foundation,  
2 form.

3 A I don't know what you're asking me. Are  
4 you asking me that if it is cytotoxic, people should  
5 know, or are you asking me is it cytotoxic?

6 Q (By Mr. Kuntz) I'm asking you if Ethicon  
7 has testing that shows that if it's cytotoxic, that  
8 should be put in the IFU and physicians should be  
9 informed about it?

10 MR. SNELL: Same objection, lacks  
11 foundation, form, vague.

12 A I would need to know more about the  
13 cytotoxicity. Is that in humans? Is that in  
14 benchwork? Is that in rats?

15 Q (By Mr. Kuntz) Have you --

16 A I can't answer that.

17 Q Have you reviewed any testing from Ethicon  
18 or been provided with any documents related to  
19 cytotoxicity testing on the Prolene mesh?

20 A Well, we have the material safety data  
21 sheet that looks at polypropylene, and that's  
22 something that we had in the exhibit -- in the orange  
23 folder, Exhibit No. 8.

24 Q Doctor, have you reviewed any testing that  
25 talks about cytotoxicity of the Prolene mesh or not?

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1           **A**     Yes.

2           **Q**     Okay. And you're saying that information  
3 is in the MSDS?

4           **A**     You know, "cytotoxicity" might not be the  
5 right word, but it's an evaluation of the  
6 composition, the hazardous identification, potential  
7 health effects.

8           **Q**     Okay. Let's just move on.

9           **A**     All right.

10          **Q**     Do you agree that the TVT IFU does not warn  
11 that there is a chronic foreign body reaction as a  
12 result of the TVT mesh?

13                 MR. SNELL: Objection, form, the document  
14 speaks for itself.

15          **A**     Yeah.

16                 MR. SNELL: If you need to get the IFU out  
17 --

18          **A**     Yeah. Let's go back to the IFU. Let me  
19 get that out.

20                 MR. KOOPMANN: Exhibit 15.

21                 THE DEPONENT: 15?

22                 MR. KOOPMANN: Right there (indicating).

23          **A**     Under Adverse Reactions, it speaks to  
24 punctures, transient local irritation, transitory  
25 foreign body response. This response could lead in

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1 extrusion, erosion, fistula formation, or  
2 inflammation.

3 So they don't specify a time frame, but,  
4 you know, I think that it's reasonable to understand  
5 that it could be either acute or chronic.

6 Q (By Mr. Kuntz) But by that statement, you  
7 believe that physicians would know that it's a  
8 chronic foreign body reaction?

9 A If someone results in having an erosion or  
10 a fistula formation, yeah, those things are  
11 representative of chronic problems.

12 Q So if somebody has mesh permanently left in  
13 their body and it's a chronic reaction, as you  
14 suggest, a physician would know that? Erosions can  
15 happen anytime in the future, correct?

16 A Can you repeat the question?

17 Q You believe that that doesn't imply  
18 transitory because erosions can happen at any time,  
19 and, therefore, physicians would know that it's a  
20 chronic foreign body reaction by that statement even  
21 though it says "transitory"?

22 A I think "transitory" is in the first  
23 sentence. The second sentence is a separate  
24 sentence. So I think that it could be transitory or  
25 chronic.

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1           **Q**     So why didn't they just place the words  
2     "chronic" in there, Doctor?

3           **A**     I don't know.

4                   MR. SNELL: Objection, form, calls for  
5     speculation.

6           **A**     I'm not going to speculate.

7           **Q**     (By Mr. Kuntz) Okay. Do you believe that  
8     there's a chronic foreign body reaction to the mesh,  
9     or do you believe it's transitory?

10          **A**     I believe in most instances it's  
11     transitory.

12          **Q**     Okay. But there are instances where it can  
13     be chronic, correct?

14          **A**     Yeah, there are probably a small subset of  
15     patients that can have a chronic reaction and where  
16     you might see inflammatory cells.

17          **Q**     Do you agree that if Ethicon knew that the  
18     TVT device was reasonably associated with  
19     dyspareunia, it should have been included in the IFU?

20                   MR. SNELL: Objection, form and foundation.

21          **A**     I think that it's pretty clear, if you read  
22     the IFU, that it warns about complications and injury  
23     to surrounding structures and organs, nerve damage,  
24     et cetera. That's going to lead to dyspareunia.

25          **Q**     (By Mr. Kuntz) Doctor, the words

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1 "dyspareunia" never appear in the IFU, do they?

2 MR. SNELL: Objection. The document speaks  
3 for itself as to what specific words appear in it.

4 A Yeah.

5 Q (By Mr. Kuntz) Doctor, do the words  
6 "dyspareunia" appear anywhere in the IFU?

7 A No. I don't see the word "dyspareunia."

8 Q Is there anywhere in the IFU that tells a  
9 patient or a doctor -- strike that.

10 Is there anywhere in the IFU that states  
11 that one's partner can be injured by the mesh?

12 MR. SNELL: Form and foundation.

13 A I think that the IFU is a warning to  
14 physicians about the precautions and adverse  
15 reactions.

16 So the IFU is written for the physician.  
17 It's not written for the patient. It's not written  
18 for the partner.

19 Q (By Mr. Kuntz) Doctor, do you think women  
20 would want to know that their partner could be  
21 injured from a product they're having implanted in  
22 them?

23 MR. SNELL: Objection, foundation, form,  
24 calls for speculation.

25 A I'm not going to answer that.

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1           **Q**        (By Mr. Kuntz)   Why?

2           **A**        I think it calls for speculation. I think  
3        women want to know what's going to happen to them.  
4        It's a rare patient that would have no pain but their  
5        partner would have pain.

6                    So I think the two things are connected.  
7        If the patient has dyspareunia, the husband may have  
8        pain as well. It's an unpleasant experience for both  
9        of them.

10          **Q**        Do you warn your patients that their  
11        partners might have pain during sexual activity  
12        before you implant a TVT device in them?

13          **A**        No, I don't.

14          **Q**        Have your consents changed over the years?  
15        Do you have more stuff in your consent now than you  
16        did in, say, 2005 for a TVT product?

17                    MR. SNELL: Form, vague. Go ahead.

18          **A**        Yeah. I follow what the FDA PHN has  
19        recommended, and the document I prepared for the AUA,  
20        I gave a list of bullet points that physicians should  
21        share with their patients when providing informed  
22        consent. So yeah, it has evolved over time.

23          **Q**        (By Mr. Kuntz) When you've been consulting  
24        with Ethicon, have you ever asked them why they  
25        haven't updated their IFU for the TVT products in

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1 relation to the FDA PHNs?

2 MR. SNELL: Objection, lacks foundation.

3 It misstates the evidence.

4 A I have not had that conversation with them.

5 They're -- they're aware of the PHN as much as I am.

6 I don't need to advise them in regards to how to

7 respond to the PHN.

8 Q (By Mr. Kuntz) Do you agree if Ethicon  
9 knew that the TVT device was reasonably associated  
10 with chronic pain, it should be included in the IFU?

11 MR. SNELL: Objection, foundation.

12 A I feel the IFU is adequate. It warns --

13 Q (By Mr. Kuntz) That's not my question,  
14 Doctor. I know --

15 A -- of any --

16 Q -- you think it's adequate.

17 (All speaking simultaneously, and  
18 reporter requested clarification.)

19 A Okay.

20 Q (By Mr. Kuntz) Agree or disagree. If  
21 Ethicon knew that the TVT device was reasonably  
22 associated with chronic pain, it should have been  
23 included in the IFU. Do you disagree or agree with  
24 that?

25 MR. SNELL: Objection, form.

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1           **A**     I think I've answered that, but I disagree  
2     with that.

3           MR. SNELL:   Can we take a break at some  
4     point, Jeff?

5           MR. KUNTZ:   Sure.

6           (Recess from 7:23 p.m. to 7:44 p.m.)

7           **Q**     (By Mr. Kuntz)   Doctor, I want to talk a  
8     little bit more about the IFUs.

9           **A**     Yes.

10          **Q**     Do you agree that patients would like to  
11     know the severity, frequency, or duration of the  
12     adverse risks that are associated with the product?

13          MR. SNELL:   Objection, foundation, form,  
14     compound.

15          **A**     Can you repeat the question?

16          **Q**     (By Mr. Kuntz)   Yeah.   I'll change it.

17                 Do you agree that patients receiving a TVT  
18     product would like to know the severity of the  
19     adverse risks listed in the IFU?

20          MR. SNELL:   Objection, foundation, calls  
21     for speculation, compound.

22          **A**     Are you asking me if that stuff should be  
23     in the IFU, or are you asking me should doctors tell  
24     patients that?

25          **Q**     (By Mr. Kuntz)   I'm asking:   Do you think

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1 patients want to know that information?

2 MR. SNELL: Same objections.

3 A I think when talking to patients about  
4 risks and benefits, if it's a risk that occurs  
5 commonly, then patients -- physicians are going to  
6 mention that to their patients.

7 Yeah, so I would agree patients want to  
8 know, but I would disagree that that's a purpose of  
9 the IFU.

10 Q (By Mr. Kuntz) Do you agree that a company  
11 cannot avoid warning of an adverse event in the IFU  
12 just because it is rare?

13 MR. SNELL: Objection, form, calls for a  
14 legal conclusion.

15 A I would disagree.

16 Q (By Mr. Kuntz) Are you an expert in IFUs?

17 A I've made contributions to IFUs, but I'm  
18 not an expert in it. No. I think it's something  
19 that's prepared by an in-house person within a  
20 corporation, but I've made contributions in terms of  
21 commentary.

22 Q Have you ever reviewed any of the FDA  
23 regulations on labeling?

24 A No.

25 Q Have you ever reviewed any of the FDA

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1 guidelines on labeling?

2 **A** No.

3 **Q** Does Ethicon put the severity of adverse  
4 risks in the IFU?

5 **A** The severity of risks or the prevalence of  
6 risks?

7 **Q** Yes.

8 **A** I don't see anything about prevalence.

9 **Q** Okay. Do you see anything in the IFU for  
10 the TVT line of products talking about the duration  
11 of the risks?

12 **A** I don't see a specific time frame  
13 mentioned. It talks about transient leg pain lasting  
14 24 to 48 hours.

15 **Q** Nothing about chronic pain in the IFU, is  
16 there?

17 MR. SNELL: Objection, form, vague, asked  
18 and answered.

19 **A** Yeah, I mentioned earlier when I said,  
20 "This response could result in extrusion, erosion,  
21 fistula formation, or inflammation."

22 Many of those issues are chronic issues  
23 that can happen over time or in a delayed fashion.  
24 So I think it speaks to it.

25 **Q** (By Mr. Kuntz) The words "chronic pain"

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1 never appear in the IFU, do they, Doctor?

2 MR. SNELL: Objection, form. Did you say  
3 "the words 'chronic pain'"?

4 MR. KUNTZ: Yes.

5 MR. SNELL: All right.

6 A Okay. I don't see the word "chronic." I  
7 see the mention of -- about punctures to vessels,  
8 nerves, bladder.

9 MR. KUNTZ: I'll move to strike.

10 Q (By Mr. Kuntz) Are the words -- "chronic"  
11 appear anywhere in the IFU?

12 MR. SNELL: Objection, form. The document  
13 speaks for itself as to the words in it.

14 Q (By Mr. Kuntz) Doctor, do you know if the  
15 word "chronic" appears anywhere in the IFU?

16 A I don't see it in the IFU, the word  
17 "chronic."

18 Q How many times does the word "transitory"  
19 appear in the IFU?

20 A The word "transitory" appears under the  
21 section Adverse Reactions.

22 Q Do you agree or disagree that the IFU must  
23 put adverse events in the context of severity and  
24 frequency?

25 MR. SNELL: Objection, form, asked and

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1 answered.

2 MR. KUNTZ: I didn't ask that exact  
3 question.

4 A Yeah, I'm going to disagree to that.

5 Q (By Mr. Kuntz) Okay. Have you ever read  
6 Pete Hinoul's trial testimony from the Bateese  
7 (phonetic) case?

8 A No, I have not.

9 Q Do you know who Pete Hinoul is?

10 A Yeah. I've authored a paper with Pete. I  
11 know him reasonably well.

12 Q You examined Mrs. Perry on December 19th?

13 A That's correct.

14 Q And you would agree that Mrs. Perry  
15 currently has pelvic pain?

16 A Yeah, I would agree that she's had chronic  
17 pelvic pain.

18 Q And you agree that when you examined her,  
19 you listed it as pain?

20 MR. SNELL: Form, vague. What pain are you  
21 talking about?

22 Q (By Mr. Kuntz) Well, you examined her and  
23 found pain in four different areas of the vagina,  
24 correct, Doctor?

25 A I'm looking at my examination right now,

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1 and I see her describing pain -- one, two, three --  
2 yeah, four different areas.

3 Q So as of December 19th, you believe she has  
4 pain in four different areas of her vagina?

5 A That's what she told me.

6 Q And, in fact, you have no reason not to  
7 believe her, correct?

8 MR. SNELL: Form.

9 Q (By Mr. Kuntz) Let me ask you this,  
10 Doctor: You're trained to determine whether patients  
11 are being honest about pain, correct?

12 A We receive very little training on that.

13 Q But part of your job is to determine  
14 whether patients are telling the truth about pain or  
15 not --

16 A Yes --

17 Q -- correct?

18 A -- that's correct.

19 Q And you fill out a psychiatric part -- or  
20 portion of your exam. You state that she answers  
21 questions appropriately within normal effects.

22 What does that mean?

23 A It means that she was never extreme about  
24 any of her answers. She never seemed angry, never  
25 seemed disturbed with me or confrontational.

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1           **Q**     Do you believe she was telling the truth  
2     about the pain that you noted in your IME?

3           **A**     I don't have an answer to that.

4           **Q**     You have to answer that question, Doctor.  
5     Do you believe --

6                   MR. SNELL: No, he doesn't have to answer  
7     -- he can answer it any way he wants.

8           **A**     It's very difficult to assess someone's  
9     ability or inability to tell the truth based on one  
10    exam.

11                   If Coleen Perry was my patient, I would  
12    eventually formulate an opinion over time, but it's  
13    very difficult on a single exam to know if the  
14    patient is telling the truth or not.

15           **Q**     (By Mr. Kuntz) So -- and you're not  
16    trained to tell whether patients are telling the  
17    truth or not when you're doing a pain exam?

18           **A**     I mentioned we have little training in  
19    that. It comes down to a gut feeling, basically.  
20    That's all it is.

21           **Q**     What's your gut feeling in this case? Was  
22    she telling the truth about her pain or not?

23           **A**     I haven't formulated an opinion on that.

24           **Q**     So you're going to give no opinion on that  
25    at trial in this case?

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1           **A**       I may give an opinion, but it's something  
2       that I'm still struggling with to determine.

3           **Q**       Doctor, this is my only chance. I am  
4       entitled to know your full opinion right now on this  
5       deposition as to what you're going to testify to at  
6       trial or not.

7                   Do you understand that?

8           **A**       What I'll testify in trial is: When I  
9       touched those four areas, she reported pain, and I  
10      graded what that pain was.

11                  I think it's going to be up to the jury to  
12      determine whether or not she was telling the truth or  
13      not.

14          **Q**       Are you going to offer an opinion as to  
15      whether she was telling the truth or not?

16                  MR. SNELL: No. He just told you the limit  
17      of his opinion right there.

18          **Q**       (By Mr. Kuntz) So you're going to say when  
19      you examined her, when you touched those areas, she  
20      reported those levels of pain?

21          **A**       That's correct.

22                  MR. KUNTZ: And, Sean, can you hand him the  
23      diagram of the vagina and mark that as an exhibit.

24                  MR. KEITH: I can. I can impress everybody  
25      how quickly I can go to it. That will be Exhibit 29.

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1 (Exhibit 29 was marked.)

2 MR. KEITH: This document that's here,  
3 where does that go? Does that go in Exhibit 8, that  
4 orange folder?

5 THE DEPONENT: This would go in the orange  
6 folder, yes.

7 MR. KEITH: Do you want to kind of get that  
8 --

9 THE DEPONENT: Sure.

10 MR. KEITH: Everything that goes in  
11 Exhibit 8, can we get that over there? Do you have  
12 anything, Burt? Did you take anything from  
13 Exhibit 8?

14 MR. SNELL: No. I just have my exhibit  
15 over here that I hand marked and my documents.

16 MR. KEITH: Those are yours.

17 MR. SNELL: This is his. I don't know what  
18 this goes to.

19 MR. KEITH: That goes in Exhibit 8. I know  
20 that for a fact.

21 (Discussion off the record.)

22 Q (By Mr. Kuntz) Doctor, I want you to mark  
23 on Exhibit 9 the four areas that you reported pain in  
24 her vagina in your IME.

25 MR. KEITH: It's Exhibit 29, Jeff. I'm

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1       sorry.

2               MR. SNELL: And to the extent you're not  
3       able to accurately mark it or depict it in this  
4       two-dimensional view, you should note that on the  
5       record. This isn't a drawing deposition. It's a Q  
6       and A deposition. Do you understand me?

7               THE DEPONENT: I do.

8               **Q**       (By Mr. Kuntz) So go ahead and mark where  
9       you believe she had pain along the midline of --

10              MR. SNELL: Objection, form. It misstates  
11       the testimony. His testimony was that that's where  
12       she reported pain.

13              MR. KUNTZ: Are you going to testify for  
14       him, Burt, or object?

15              MR. SNELL: In California, we have to make  
16       actually substantive form objections.

17              MR. KUNTZ: Oh.

18              MR. SNELL: At least that's what Barry  
19       keeps slapping me for.

20              MR. KEITH: Barry is the quiet one at the  
21       end of the table.

22              (Discussion off the record.)

23              **A**       Okay. I've marked the -- Exhibit 29, the  
24       four areas that I described in my physical exam.

25              **Q**       (By Mr. Kuntz) Okay. And what are those

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1 four areas?

2 **A** So the first area I marked was the  
3 posterior scar and perineorrhaphy area, and that area  
4 is labeled "Cyst and posterior scar: 8 out of 10."

5 The next area is X on the anterior wall  
6 near the urethra, and that's labeled "Anterior wall:  
7 5 out of 10." And then there's an area on the right  
8 lateral vaginal wall labeled "4 out of 10." There's  
9 an X there. And then there's an X on the left  
10 lateral wall labeled "4 out of 10."

11 **Q** I want you to draw a line where the sling  
12 was placed in her.

13 **MR. SNELL:** I'm going to object to making  
14 the witness do that on a two-dimensional document as  
15 opposed to three-dimensional.

16 **MR. KUNTZ:** You can object. Go --

17 **MR. SNELL:** This isn't a drawing  
18 deposition. You can ask him questions, but I'm going  
19 to tell this witness not to draw something in  
20 two-dimensional.

21 **Q** (By Mr. Kuntz) Doctor, go ahead and mark  
22 where the sling was placed.

23 **A** I've been instructed not to do that. I'm  
24 not going to do that.

25 **MR. KUNTZ:** You can't instruct him not to

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1 do that, Burt. There's absolutely no basis for that  
2 objection.

3 MR. SNELL: You tell me where in California  
4 it's proper to have a witness do a drawing at a  
5 deposition. A deposition is the question and answer  
6 session. He's --

7 (All speaking simultaneously, and reporter  
8 requested clarification.)

9 MR. SNELL: He has provided a full IME  
10 report to you that describes all of his findings.

11 MR. KUNTZ: Put a diagram in the IME, or  
12 you can put him on the stand and have him draw on  
13 whatever you want. I will keep this deposition open  
14 or sit here all night until he makes that drawing.

15 You cannot tell him not to make that  
16 drawing where the sling goes on that diagram. That's  
17 an absolutely improper objection --

18 MR. SNELL: That -- this diagram --

19 (All speaking simultaneously, and reporter  
20 requested clarification.)

21 MR. SNELL: The diagram --

22 MR. KEITH: Let him finish.

23 MR. SNELL: The diagram is not an adequate  
24 depiction of her three-dimensionally. You have this  
25 printed out from some Web site. I don't know where.

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1 I think it's going to misconstrue his opinion and  
2 testimony.

3 MR. KEITH: Okay. Go, Jeff.

4 MR. KUNTZ: You can object all you want for  
5 the record, and you can fix it with the judge, if you  
6 believe that's the rule. And you can ask him on  
7 direct to show whatever diagram you want. And if  
8 this is used, you can redirect him.

9 Q (By Mr. Kuntz) Doctor, draw the line where  
10 the sling went.

11 MR. SNELL: He can mark an X where the  
12 sling was, but I'm not telling him to draw a line  
13 where the sling went because this thing is not in any  
14 type of three-dimensional form.

15 Q (By Mr. Kuntz) Doctor, do you ever use  
16 non-three-dimensional models or diagrams to show your  
17 patients things?

18 A I've brought an exhibit with me -- it's in  
19 Exhibit 8 -- of some drawings that I use with my  
20 patients when describing mid-urethral sling  
21 procedures to them. I'm going to go ahead and get  
22 that out of the orange folder that's already been  
23 marked as Exhibit 8.

24 Q Great. Mark where her sling went on that,  
25 and then mark all the areas of pain on that diagram,

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1 too.

2 **A** Okay. Great.

3 Well, on this document from Ethicon, you  
4 know, there's already a picture of the sling. I  
5 mean, I can circle what the sling looks like, but  
6 it's already marked on the drawings.

7 **Q** Okay. Show me the four areas of pain on  
8 that drawing as well.

9 **A** Okay. This is glossy, so it's going to be  
10 a little hard to mark up, but we'll see what we can  
11 do.

12 MR. SNELL: I'm going to object to the  
13 depiction again. It's not adequate. It doesn't  
14 demonstrate the areas of her colporrhaphy and  
15 perineoplasty scarring. So there you are.

16 MR. KEITH: What page -- you're going to  
17 mark it so we'll know clearly. Jeff, he's in the --  
18 what I would describe as a bound flip board, and it  
19 doesn't have page numbers, does it, Doc?

20 THE DEPONENT: The problem with me marking  
21 this, is this is something I use in my practice. I  
22 really --

23 MR. SNELL: He's not going to mark it.

24 THE DEPONENT: I really don't care to  
25 destroy it.

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1 MR. SNELL: You don't have to mark it up  
2 then.

3 MR. KEITH: Well, go make a copy of it  
4 then.

5 MR. KUNTZ: You don't have another copy of  
6 it?

7 MR. SNELL: Let me see if I can make a  
8 copy. That's a good point.

9 THE DEPONENT: Okay. We can make a copy of  
10 it.

11 MR. KEITH: Jeff, he has not marked on the  
12 Exhibit 29 yet, and I don't want Burt leaving yet  
13 until -- but I just want you to know he still hasn't  
14 marked on Exhibit 29.

15 MR. SNELL: Why don't you just ask -- I  
16 don't have a problem if you have him mark like an X  
17 where the sling was, but are you trying to ask him to  
18 draw where the sling incision was? Because you have  
19 given him this 2-D model that I think an X is fine.

20 I have no problem with marking an X, but  
21 trying to redraw an incision on this, that -- I have  
22 a problem with that.

23 MR. KUNTZ: That's not what I was saying,  
24 Burt. I was saying mark an X. I'm not saying --

25 MR. SNELL: Oh, okay. Then if you want to

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1 mark an X, then I'm okay with that.

2 (All speaking simultaneously.)

3 MR. KEITH: Let him finish.

4 MR. KUNTZ: I was asking where the sling  
5 went.

6 MR. SNELL: Okay. I'm sorry. I  
7 misunderstood you.

8 MR. KUNTZ: I'm not trying to say do a  
9 freak'n, you know, artist rendition.

10 MR. SNELL: That's fine. That's fine. I  
11 misunderstood you. Yeah. Go ahead and mark an X  
12 wherever the sling would have been, if you can. If  
13 you can't, I mean, you've got to tell us.

14 **A** Well, the pen that Sean gave me was in  
15 blue, so I'm going to mark in black just to try to  
16 distinguish the pain and then the sling.

17 And instead of putting an X, why don't I  
18 just draw like a couple little solid dots just to try  
19 to distinguish.

20 **Q** (By Mr. Kuntz) Perfect.

21 MR. KEITH: I'm looking at it. Yeah. Go  
22 ahead and do that. Okay. So the doc drew four dots  
23 across the --

24 THE DEPONENT: Five.

25 MR. KEITH: -- five dots from right to left

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1 across the upper third of -- kind of where it says  
2 "urethra," kind of in that area. Drew five dots. It  
3 looks -- so --

4 Q (By Mr. Kuntz) And, Doctor, these are the  
5 four areas that she reported pain to you during your  
6 examination?

7 A Yeah. I'm going --

8 MR. SNELL: Objection, form.

9 A I'm going to continue to just draw this  
10 out. There's no picture of the obturator foramen,  
11 but I'm just drawing how it would be lying inside the  
12 body.

13 MR. KEITH: He's talking about the sling at  
14 this point.

15 MR. KUNTZ: Gotcha.

16 MR. KEITH: All right. Jeff?

17 MR. SNELL: Put that away. Listen to his  
18 questions. I'll take care of that.

19 Q (By Mr. Kuntz) Doctor, you've marked the  
20 four areas where you believe -- strike that.

21 You marked the four areas that she reported  
22 pain?

23 A Yes.

24 Q And in your IME, you believe that she needs  
25 certain treatment for her current pain conditions,

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1 correct?

2 MR. SNELL: Objection, vague.

3 A I have assessment and opinions at the end,  
4 if you want me to go through those.

5 Q (By Mr. Kuntz) Right. What are the things  
6 you believe she needs for treatment for her current  
7 pain condition that you list on Page 8 of your IME?

8 A So you're speaking to No. 2, pelvic pain?

9 Q Correct.

10 A She may consider pharmacologic therapy,  
11 vaginal massage, vaginal suppositories, physical  
12 therapy. Tramadol is what she's using currently.

13 Q So those are the treatments you believe she  
14 needs for her current issues related to pain?

15 MR. SNELL: Objection, form. It misstates.

16 A Those are some potential options that she  
17 can consider.

18 Q (By Mr. Kuntz) Okay. What type of  
19 pharmacological therapy do you think she needs?

20 MR. SNELL: Objection, form. It misstates.

21 A Pharmacologic therapy could include  
22 nonsteroidal anti-inflammatory drugs. The vaginal  
23 suppositories could be a muscle relaxant. For  
24 instance, like Valium. Pharmacologic therapy could  
25 also include trigger point injection of an anesthetic

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1 and a steroid. Topical creams may be considered like  
2 vaginal estrogen, lidocaine, jelly, lubricants.

3 Q (By Mr. Kuntz) What about vaginal massage?  
4 How often do you think she should get vaginal  
5 massage?

6 MR. SNELL: Again, objection, form. It  
7 misstates his testimony.

8 A I said that's something she can consider,  
9 but I don't have a specific regimen for her.

10 Q (By Mr. Kuntz) What is vaginal massage?  
11 Is that an invasive procedure?

12 A No, I wouldn't consider it any more  
13 invasive than, you know, a sexual encounter.

14 Q What type of physical therapy do you  
15 believe she should consider?

16 A Physical therapy could include heat-based  
17 therapy, ultrasonic therapy, electrical therapy with  
18 TENS unit.

19 It may be directed at the vagina. It can  
20 be directed at her groin. It can be directed at her  
21 lower back, her SI joints. So that might include  
22 manipulation of the sacroiliac joints. It might mean  
23 vaginal adjustments or manipulation.

24 So there's a lot of overlap between massage  
25 and therapy. Generally if it's massage, it's

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1 performed by a massage therapist. If it's physical  
2 therapy, I'm speaking to that provided by a licensed  
3 physical therapist.

4 Q Do you believe smoking is a  
5 contraindication for the use of the TVT Abbrevio?

6 A No.

7 Q Do you put the TVT Abbrevio in smokers?

8 A I discuss with them that it's a risk  
9 factor, but if they accept the risk, then I'm  
10 comfortable doing the surgery.

11 Q What's the conversation you have with them  
12 exactly?

13 A Especially in today's environment, I go  
14 over the risks and benefits of the procedure and I  
15 try to help identify who may be an appropriate  
16 candidate, who may not be an appropriate candidate.

17 Q Do you -- in your consent or that risk  
18 discussion, do you write those down in your consent?

19 A I don't write it down in my consent. I  
20 don't write risk factors in the consent. My consent  
21 has the goals of the procedure, the risks of the  
22 procedure, alternatives to the procedure, what  
23 happens if you decide to do nothing.

24 You know, I discuss the anesthesia and  
25 those risks, general medical risks, but I don't go

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1 over risk factors of the surgery. That's part of the  
2 discussion. The risk factors, that's not part of the  
3 informed consent. That might be part of my patient  
4 counseling.

5 Q Have you ever reviewed any documents from  
6 Ethicon that state the TVT Abbrevio should not be used  
7 in smokers?

8 A I've never seen that stated anywhere in  
9 their literature.

10 Q Do you believe that Mrs. Perry's smoking  
11 contributed to her erosion?

12 MR. SNELL: Form. It misstates prior  
13 testimony.

14 A I believe it's one of many factors that was  
15 contributory.

16 Q (By Mr. Kuntz) Can you state to a  
17 reasonable degree of medical certainty whether her  
18 smoking contributed to her erosion?

19 MR. SNELL: Objection, form. It misstates.  
20 He said she has an exposure, not an erosion. That's  
21 my form objection, if you want to clean it up.

22 MR. KUNTZ: Okay.

23 MR. SNELL: I'm just trying to help you out  
24 because that's the only basis for my objection.

25 Q (By Mr. Kuntz) You don't believe "erosion"

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1 is an appropriate term at all, do you, Doctor?

2       **A**     I believe it's a term that we use commonly,  
3 but in written communications and in critical  
4 discussions, I try to use the most accurate term.

5       **Q**     Well, shouldn't Ethicon use the most  
6 accurate terms in their instructions for use and  
7 promotional documents?

8       **A**     I think that, you know, you try to use  
9 common language, you know, terms that can be  
10 translated into multiple languages. So it's a  
11 difficult process.

12       **Q**     Do you believe that Ethicon should use the  
13 accurate terms in their IFUs or promotional  
14 materials? Do you think it's appropriate for them to  
15 use "erosion" when you don't use that word?

16       **A**     I didn't say I don't use that word. I said  
17 I didn't use that word in the IME. I don't use that  
18 in my publications, but it's a word that comes out of  
19 my mouth at least every day.

20       **Q**     Okay. Do you believe that Mrs. Perry's  
21 smoking caused or contributed to her exposure?

22       **A**     Yes.

23       **Q**     And you can say that to a reasonable degree  
24 of medical certainty?

25       **A**     Yes, I can.

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1           **Q**     Do you believe Dr. Luu is below the  
2     standard of care for implanting or prescribing the  
3     TVT Abbrevo to a patient that smokes?

4           **A**     No, I don't believe that he fell below the  
5     standard of care in offering this procedure to her.

6           **Q**     Do you believe Dr. Luu fell below the  
7     standard of care in any respect in this case?

8           **A**     I have some serious concerns with the way  
9     he performed the procedure with options that he  
10    didn't offer her. I have some concerns on her  
11    evaluation, her workup, her procedure selection. So  
12    I have some concerns.

13           MR. SNELL: We're not putting him up to say  
14    he breached the standard of care, if that's what  
15    you're asking.

16           MR. KUNTZ: Right.

17           **Q**     (By Mr. Kuntz) So you have no opinions  
18    that he actually fell below the standard of care in  
19    any respect?

20           **A**     I'm not going to offer that opinion, but I  
21    do think that there were some things where the  
22    procedure was done that may have led her to be more  
23    likely to have an exposure.

24           **Q**     Well, Doctor, it's a real simple question.  
25                   Do you believe he fell below the standard

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1 of care in any respect or not?

2 **A** I'm not going to offer an opinion that he  
3 fell below the standard of care. So my answer would  
4 be no.

5 **Q** Are you going to offer an opinion that  
6 Dr. Singh fell below the standard of care in any  
7 respect?

8 **A** Dr. Singh?

9 **Q** Yes.

10 **A** No.

11 **Q** What literature do you rely on to support  
12 your statement that 40 percent dyspareunia rate after  
13 posterior colporrhaphy?

14 **A** There is a number of articles. The Jameson  
15 article from 1996 is an important one. The Arnold  
16 article, the Karram article.

17 So I believe that the incidence is  
18 somewhere between 20 and 46 percent.

19 **Q** 20 percent and 46 percent?

20 **A** Somewhere in that range.

21 **Q** Do you know -- in any of the cases that  
22 reported 40 percent and 46 percent, did they plicate  
23 the levators in those procedures?

24 **A** It's hard to know exactly what were done in  
25 some of the procedures. The incidence is variable,

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1 depending on the type of posterior colporrhaphy,  
2 whether or not levators were plicated, whether or not  
3 it was site specific, whether or not it was just a  
4 plication, was the peroneal body involved. So that's  
5 at least the variability.

6 Q Would you agree that if the levators were  
7 plicated in those procedures or in those studies,  
8 that the rate of dyspareunia would increase?

9 MR. SNELL: Form, foundation.

10 A Yeah. I don't plicate the levators, and I  
11 think that's something that you have to be careful  
12 about.

13 Q (By Mr. Kuntz) And you don't plicate the  
14 levators because it would increase the rate of  
15 dyspareunia or the chances of dyspareunia, correct?

16 A It would depend on the patients, but on  
17 most patients, I don't. On older patients who are  
18 not sexually active, plicating the levators would  
19 improve your outcome in terms of not having recurrent  
20 prolapse.

21 So it's individualized to the patient,  
22 depending on what their goals are for the procedure.

23 Q That wasn't my question, Doctor.

24 Would plicating the levators increase the  
25 chance for dyspareunia and increase the rates of

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1 dyspareunia?

2 **A** The answer would be yes.

3 **Q** Okay. And Dr. Luu did not plicate the  
4 levators in his posterior colporrhaphy in this case,  
5 did he?

6 **A** I'm going to get Dr. Luu's operative report  
7 out.

8 **Q** You don't -- you don't know as we sit here  
9 right now?

10 **A** I don't believe he did, but I want to be  
11 certain of that, as I'm going to make testimony to  
12 that.

13 MR. KEITH: He's looking at Exhibit No. --  
14 what do you think it is, Doc?

15 THE DEPONENT: Seven.

16 MR. KEITH: He is looking at Exhibit No. 7.

17 **A** Okay. So I have Dr. Luu's operative report  
18 in front of me. It's part of Exhibit 7 and at the  
19 very -- that's Dr. Allen's. I think I've got it.

20 So when describing the posterior repair,  
21 there's not a lot of detail, but Dr. Luu says that  
22 the endopelvic fascia was reinforced with 2-0 Vicryl.  
23 Posterior vaginal mucosal incision. Re-approximated  
24 with 2-0 Vicryl running-locking. Bulbocavernosus  
25 muscle was re-approximated with 2-0 Vicryl.

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1           None of those structures I would consider  
2   as part of the levator complex. A levator complex,  
3   in terms of the muscle, is the iliococcygeus and  
4   pubococcygeus muscles.

5           **Q**     (By Mr. Kuntz) So is -- the answer to my  
6   question is: You agree that he did not plicate the  
7   levators?

8           MR. SNELL: Form.

9           **A**     I agree.

10          **Q**     (By Mr. Kuntz) Okay. Would you agree that  
11   Dr. Luu's procedure was a site-specific repair?

12          MR. SNELL: Form.

13          **A**     No, I disagree with that.

14          **Q**     (By Mr. Kuntz) You disagree with that?

15          **A**     Yeah. He never mentions any -- finding any  
16   specific defects. He did a compensatory repair.  
17   That's the type of repair he did.

18          **A**     Are you speaking to the posterior wall?

19          **Q**     Yes.

20          MR. SNELL: Where are these articles at?  
21   Do you have them?

22          **Q**     (By Mr. Kuntz) Do you agree with me the  
23   posterior repair -- or I guess you -- strike that.  
24                You disagree that the posterior repair on  
25   Mrs. Perry by Dr. Luu was a site-specific repair?

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1           **A**       Yeah, I disagree with that.

2           **Q**       Okay. Do you believe that the TVT Abbrevio  
3 mesh contributed in any way to her current  
4 conditions?

5           **A**       No, I don't believe it's contributed to her  
6 current condition.

7           **Q**       Okay. So the mesh that eroded -- the TVT  
8 Abbrevio mesh did not contribute to any of her current  
9 injuries, correct, in your opinion?

10                   MR. SNELL: Objection, form. He just  
11 answered that, asked and answered.

12           **Q**       (By Mr. Kuntz) Okay. But her smoking  
13 contributed to it, correct?

14           **A**       Her smoking contributed to the wound  
15 dehiscence that she had anteriorly.

16           **Q**       So that's a "yes"?

17                   MR. SNELL: Objection. It misstates.

18           **A**       No. It's not a "yes." The smoking  
19 contributed to the healing abnormality that existed  
20 in her.

21           **Q**       (By Mr. Kuntz) Did you note in Dr. Singh's  
22 deposition, what he testified to, about the healing  
23 of her wound two months after the procedure?

24           **A**       Yeah, I'm familiar with the time line and  
25 what Dr. Singh had testified. I believe he was the

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1     only physician up until that point that ever examined  
2     her after Dr. Luu's surgery. So we'll have to go on  
3     Dr. Singh's testimony.

4           **Q**     Okay. And if he believes that two months  
5     after the procedure his exam showed that she was  
6     healed, do you disagree with that?

7           MR. SNELL: If you need to get his records,  
8     get his records out.

9           **A**     At eight weeks, Dr. Singh saw her at four  
10    weeks and then again at eight weeks. And sometime in  
11    and around that -- after that eight-week visit, she  
12    saw Dr. Singh, and he noted there was a mesh  
13    exposure.

14           So I would say somewhere between that  
15    second postop visit -- probably within a few days  
16    Coleen Perry complained of pain when she had sexual  
17    intercourse.

18           **Q**     (By Mr. Kuntz) That's not even close to my  
19    question, Doctor.

20           Do you know one way or another what  
21    Dr. Singh said about Mrs. Perry's healing issues?

22           MR. SNELL: We have the records, I think,  
23    here. Get the records.

24           **A**     Let me go ahead and get Dr. Singh's  
25    deposition in front of me.

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1           **Q**       (By Mr. Kuntz) Do whatever you want.

2                   When you were reviewing and preparing for  
3 this deposition and forming your opinions in this  
4 case, did you take into account what Dr. Singh said  
5 about Mrs. Perry's healing condition?

6           **A**       Yeah, I took into my opinion Dr. Singh's  
7 reports. I did read his office notes.

8           MR. SNELL: I might have his records on  
9 this.

10          MR. KOOPMANN: I do.

11          MR. SNELL: Do you have hard copies?

12          MR. KEITH: What are we looking for?

13          MR. SNELL: Dr. Singh's records. I don't  
14 know if we -- if those are printed out in a hard  
15 copy. Do you see any records over there?

16          MR. KEITH: No.

17                   (Discussion off the record.)

18          THE DEPONENT: We could open up one of the  
19 CDs that's marked as an exhibit.

20          MR. SNELL: That's a good idea. Hold on.

21                   (Discussion off the record.)

22                   (Mr. Keith left the room.)

23           **Q**       (By Mr. Kuntz) Okay. What is your  
24 understanding as to Dr. Singh's opinion on  
25 Mrs. Perry's healing issues?

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1           **A**     You know, the notes are hard to read.  
2     They're handwritten. With that said, I'm looking at  
3     the March 24, 2011 visit. That's one day post-op.  
4     He didn't examine her that day. He saw her just to  
5     remove the Foley catheter.

6                     April 4, 2011, it says, "Cuff healing," and  
7     that's on April 4th. So I'm not sure what he's  
8     describing as the cuff because she didn't have a  
9     hysterectomy, but he says, "Cuff healing."

10                    On April 15th, she's still having  
11    yellowish, abnormal discharge -- yellowish discharge  
12    less than before.

13                    (Mr. Keith entered the room.)

14           **A**     Physical exam. It says, "Normal  
15    discharge." It looks like it says, "Incision  
16    stable."

17                    And then we jump to May 16, 2011. It says,  
18    "No evidence of mesh erosion. Stitches intact." So  
19    that's -- three months after surgery I guess there's  
20    still stitches there.

21           **Q**     (By Mr. Kuntz) So, Doctor, do you know by  
22    any of the information you reviewed in this case and  
23    provided to you by defense counsel what Dr. Singh's  
24    opinion is with respect to Mrs. Perry's healing  
25    issue? Yes or no?

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1 MR. SNELL: Form, vague.

2 A I don't believe Dr. Singh formulated an  
3 opinion on why she had a healing abnormality.

4 Q (By Mr. Kuntz) Do you know if Dr. Singh  
5 formulated an opinion that she did not have a healing  
6 issue? Do you know one way or the other?

7 A I know he was concerned about the diet she  
8 was on.

9 Q That's not my question. We're talking  
10 about the healing issue, Doctor.

11 Do you know one way or another, as we sit  
12 here today, as you have been prepared to offer your  
13 opinions in this case, whether Dr. Singh had an  
14 opinion or not whether she had healing issues that  
15 led to her erosion?

16 MR. SNELL: Objection, form, asked and  
17 answered.

18 A I don't believe he had an opinion.

19 Q (By Mr. Kuntz) Okay. Do you know whether  
20 Dr. Singh had an opinion whether Mrs. Perry's diet or  
21 weight loss led to her exposure?

22 A I know that he was concerned about her  
23 weight loss, but I don't believe he stated in his  
24 deposition or in the medical record that that was the  
25 cause.

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1           **Q**     And you do believe that her rapid weight  
2     loss and diet was partly -- part of the cause of her  
3     erosion, correct?

4           **A**     Correct.

5                   MR. SNELL:   Form.   Hold on.   Form as to  
6     "erosion."

7           **Q**     (By Mr. Kuntz)   You believe that her rapid  
8     weight loss and diet led to her exposure, correct?

9           **A**     Correct.

10          **Q**     And do you know whether Dr. Singh had an  
11     opinion as to whether her weight loss and diet led to  
12     her exposure?

13          **A**     I believe we answered that, but I think he  
14     was concerned about the 19-pound weight loss, and  
15     that was in and around the time he discovered the  
16     exposure, but I don't believe he offered an opinion  
17     that that was the cause.

18          **Q**     If he offered an opinion -- okay.   So you  
19     disagree with Dr. Singh then?

20                   MR. SNELL:   Objection, foundation, form.

21          **A**     Disagree with what statement that he made?

22          **Q**     (By Mr. Kuntz)   You say that the weight  
23     loss and diet led to her exposure or contributed to  
24     it.   Dr. Singh says it did not.   Do you disagree with  
25     Dr. Singh?

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1 MR. SNELL: Objection, foundation.

2 A Dr. Singh never stated one way or another.

3 Q (By Mr. Kuntz) Okay. If Dr. Singh did, in  
4 fact, state that he never had a concern that her  
5 fluctuation of weight could have caused a problem  
6 with her implant, do you disagree with that  
7 statement?

8 A I would then, yes.

9 Q Okay. And if Dr. Singh stated that he does  
10 not believe that her healing issues related to her  
11 exposure or contributed to her exposure, you would  
12 disagree with Dr. Singh?

13 A I would, yes.

14 Q Okay. And he was the person there treating  
15 her at the time that these issues were taking place,  
16 correct?

17 A That's correct, but Dr. Singh is not a  
18 surgeon. He doesn't even perform surgery.

19 MR. KUNTZ: Move to strike.

20 Q (By Mr. Kuntz) Tell me exactly what the  
21 hCG diet is.

22 A The hCG is human chorionic gonadotropin.  
23 It's a popular diet these days amongst women. It's a  
24 diet that I know a number of institutions have  
25 concerns about.

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1           So the effect of that diet in treating  
2   obesity is something that causes nutritionists/  
3   dietitians concern. I think it would be described as  
4   a fad diet.

5           **Q**     How is the hCG diet administered?

6           **A**     Administered?

7           **Q**     Yeah.

8           **A**     I believe that they get either a shot or an  
9   infusion of the hormone.

10          **Q**     Is it intermittent or continuous?

11          **A**     It would be intermittent.

12          **Q**     Do you believe that Mrs. Perry had enough  
13   hormones to avoid the catabolic state? Do you have  
14   an opinion on that one way or another?

15          **A**     I believe that her body was put in a  
16   catabolic state by the hCG diet. That's my opinion.

17          **Q**     What evidence do you have to support that  
18   she was in a catabolic state?

19          **A**     That would be based on the review of the  
20   records of her weight loss. It would be based on her  
21   complaints to Dr. Singh, that she felt light-headed;  
22   she had blurred vision; she just was not feeling  
23   well, having headaches.

24          **Q**     Are you critical of Dr. Singh's decision to  
25   offer Ms. Perry the hCG diet after her mesh implant?

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1           **A**       Yes, I'm concerned about that.

2           **Q**       Do you believe that Dr. Singh fell below  
3       the standard of care in prescribing the hCG diet  
4       after her implant?

5                   MR. SNELL: Objection, form. He's already  
6       testified he's not saying he's below the standard of  
7       care.

8           **A**       I don't believe he was below the standard  
9       of care, but it's certainly not something I would  
10      have prescribed.

11          **Q**       (By Mr. Kuntz) Do you have any idea the  
12      types of proteins and vitamins that Mrs. Perry was  
13      using while she was on the hCG diet?

14          **A**       I am aware that she was getting vitamin C  
15      infusions, amongst other things.

16          **Q**       What hormones was Mrs. Perry on when she  
17      was on the hCG diet?

18          **A**       Well, she has hypothyroidism. And so she  
19      was getting thyroid replacement. That's something  
20      that she had been on chronically at the  
21      recommendation of Dr. Mathur. Also progesterone. I  
22      believe that she had been on that for quite some time  
23      at the recommendation of Dr. Mathur.

24          **Q**       Do you have any literature on your reliance  
25      list that supports that cysts can spontaneously

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1 appear and disappear within weeks?

2 **A** I don't believe I have it on my reliance  
3 list, but I think that's common knowledge in terms of  
4 surgical scars and wound healing.

5 **Q** So you believe that she had a cyst that  
6 could appear and disappear within weeks, correct?

7 **A** Yeah. I think that that's very common.  
8 These go through cycles where they may drain  
9 spontaneously and then reoccur.

10 **Q** Okay. So like today, she might not have  
11 that cyst, correct?

12 **A** That's a possibility.

13 **Q** Okay. And did anybody ever -- before the  
14 time you did your IME -- ever note this cyst in any  
15 of the records you reviewed for Mrs. Perry?

16 **A** I don't see any note, but I don't know if  
17 anybody ever looked at the posterior wall after  
18 Dr. Allen.

19 **Q** Did Dr. Allen ever notice a cyst in her  
20 posterior wall?

21 **A** No.

22 **Q** Did Dr. Margolis, in his IME, note a cyst  
23 in her posterior wall?

24 MR. SNELL: Objection, form. He didn't  
25 note anything on the wall. I'm going to -- that's

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1 just incomplete.

2 **A** I don't believe he examined the posterior

3 --

4 MR. SNELL: Calls for speculation.

5 **A** -- wall.

6 MR. SNELL: Calls for speculation.

7 **Q** (By Mr. Kuntz) Safe to say of all the  
8 depositions, all the records you've reviewed in this  
9 case, you're the only person to ever note this  
10 disappearing/appearing cyst?

11 MR. SNELL: Objection, form. It  
12 mischaracterizes the doctor's opinion and description  
13 of the cyst. Go ahead.

14 **Q** (By Mr. Kuntz) Doctor, you're the only  
15 person in this case of all the doctors that have ever  
16 treated Mrs. Perry that have noted this cyst,  
17 correct?

18 **A** Correct.

19 **Q** And it's your testimony that this cyst can  
20 appear and disappear and reappear, correct?

21 MR. SNELL: Objection, form. I think that  
22 misstates again.

23 **A** It would be nice to examine her, you know,  
24 multiple times, you know, over time; but I know, at  
25 least when I examined her on December 19th,

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1       unequivocally I detected a cyst along the posterior  
2       colporrhaphy perineorrhaphy scar.

3           **Q**       (By Mr. Kuntz)   And do you believe at one  
4       time that her husband was suffering injury from the  
5       mesh exposure?

6           MR. SNELL:   Objection, form, foundation,  
7       "suffering."

8           **A**       I believe the husband had complaints.   I  
9       wouldn't characterize it as an injury.

10          **Q**       (By Mr. Kuntz)   Okay.   So he had  
11       complaints.   What were his complaints of?

12          **A**       He had mentioned that he felt like he was  
13       scratched.

14          **Q**       Have you ever seen any internal Ethicon  
15       documents or complaints from patients related to a  
16       husband being scratched on the penis during sex  
17       because of mesh exposures?

18          **A**       No, I'm not aware of that.

19          **Q**       Do you know how often those have been  
20       reported to Ethicon, those types of injuries?

21          MR. SNELL:   Objection, form, "injury."   It  
22       mischaracterizes.

23          **Q**       (By Mr. Kuntz)   Okay.   Doctor, do you think  
24       an abrasion on a man's penis is an injury?

25          **A**       As much as, you know, a little cut on your

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1 face from shaving. I mean, it depends on how you  
2 describe the word "injury." I think that's a very  
3 strong description.

4 Q What would you classify -- what would you  
5 call a scrape or abrasion on the penis? How would  
6 you classify that?

7 A I would use those exact words, "a scrape"  
8 or "an abrasion."

9 Q Okay.

10 A I don't believe anybody ever examined that.  
11 I don't see any medical records to support that that  
12 ever happened. I don't see that he was ever examined  
13 by his physician to document that there was an  
14 abrasion.

15 Q Do you think he's telling the truth when he  
16 says that?

17 A I have some concerns about his  
18 truthfulness.

19 Q So you think he's lying?

20 MR. SNELL: Form. It misstates. Go ahead.

21 A I think that that complaint is something  
22 that he either read on the Internet or was fed to  
23 him.

24 Q (By Mr. Kuntz) You have no basis for  
25 making that statement, do you?

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1           **A**       I made the statement, so I must have some  
2       basis for it.

3           **Q**       Did he report those injuries before or  
4       after this lawsuit was filed?

5           **A**       That's hard to know. I believe that it was  
6       afterwards, but I can only go on his deposition. Who  
7       did he report the injuries to?

8           **Q**       Doctor, do you know if he reported any of  
9       these injuries or Mrs. Perry reported any of those  
10      injuries prior to the time this lawsuit was filed?  
11      Yes or no?

12               MR. SNELL: Form objection. It misstates,  
13      "injuries" again. Compound as to him or Mrs. Perry.

14           **A**       I can see in the medical record, on  
15      November 10, 2014, from Dr. Allen, that it was  
16      mentioned to Dr. Allen. It says, "Husband complains  
17      of some abrasion."

18           **Q**       (By Mr. Kuntz) Did you see it anywhere  
19      else in her records prior to 2014?

20           **A**       I would like to go to Dr. Singh's record  
21      and look at Dr. Singh's record to see if that was  
22      mentioned, when Mrs. Perry was referred to Dr. Allen  
23      when the exposure was discovered.

24               MR. KEITH: And for the record, the doctor  
25      is looking at Burt's computer, which has Dr. Singh's

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1 records opened.

2       **A**       So there's a note on September 7th. It  
3 says, "Complains of feeling something sticking out of  
4 her vagina. Patient had TOT 3-2011."

5       **Q**       (By Mr. Kuntz) What date is that record?

6       **A**       This is a note from Dr. Singh, September 7,  
7 2011. "Physical exam: Mesh erosion 2 centimeters at  
8 anterior wall."

9       **Q**       In any event, you think that Mr. Perry was  
10 seeded with this information about having an abrasion  
11 on his penis?

12               MR. SNELL: Objection, form. It misstates.

13       **A**       What I'm going to state is that I don't see  
14 that he brought that complaint up or that it's ever  
15 noted in the medical record until November 10, 2014.

16       **Q**       (By Mr. Kuntz) Okay. You don't have an  
17 opinion in this case to a medical degree of --  
18 reasonable degree of medical certainty about her  
19 current condition or her current incontinence  
20 condition, correct?

21       **A**       Do I have an opinion about a current  
22 incontinence condition? Is that the question?

23       **Q**       Yes.

24       **A**       Okay. What I said in my IME is that her  
25 urinary incontinence is unspecified, meaning

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1 uncharacterized.

2           **Q**     So you can't say what it is one way or the  
3 other, correct, to a reasonable degree of medical  
4 certainty?

5           MR. SNELL: Objection. It misstates.

6           **A**     What do you mean by "one way or another"?

7           **Q**     (By Mr. Kuntz) You believe that you need  
8 to do more testing and urodynamics need to be done in  
9 order to determine her current state of incontinence?

10          **A**     If she was my patient, that's what I would  
11 do next.

12          **Q**     And when you performed your cough procedure  
13 to determine incontinence, it's inconclusive because  
14 she might have voided immediately before the exam,  
15 correct?

16          **A**     That's --

17          MR. SNELL: Form.

18          **A**     The cough test would only rule things in.  
19 It doesn't rule it out.

20          **Q**     (By Mr. Kuntz) Did you tell her to use the  
21 restroom before her exam?

22          **A**     I asked her if she would like to use the  
23 restroom. I didn't tell her to use the restroom.

24          **Q**     And you'd agree you have to have at least  
25 200 ccs in the bladder for the cough test to be

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1 representative, correct?

2       **A**       There's a lot of pitfalls to the cough  
3 test. I would agree to that.

4       **Q**       Did you do that test when she was standing  
5 up or laying down?

6       **A**       She was laying down.

7       **Q**       And she did use the restroom prior to the  
8 procedure, correct?

9       **A**       Correct.

10               MR. SNELL: I'm going to note on the record  
11 an objection as to the questioning of this witness as  
12 to the cough test only as if he was given the option  
13 of doing urodynamics because plaintiff's counsel  
14 insisted that the exam only consist of a history, a  
15 physical exam, and plaintiff's counsel did not give  
16 the opportunity for any type of urodynamic testing.

17               MR. KUNTZ: Are you done testifying?

18               MR. SNELL: No, no, no. I'm not  
19 testifying. I'm just making my record, Jeff. That's  
20 all I'm doing. Go ahead.

21               MR. KUNTZ: A lot more than that. You know  
22 that, but that's all right.

23               MR. SNELL: No, no, no. That's purely a  
24 record statement. Go ahead.

25       **Q**       (By Mr. Kuntz) What literature can you

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1 point to that discusses cysts that disappear and  
2 reappear, Doctor?

3 MR. SNELL: Objection, form, asked and  
4 answered.

5 A What literature? I think you can look at  
6 multiple Web sites, textbooks. It's well described  
7 that you can have cysts in a prior scar and an  
8 incision.

9 MR. KUNTZ: I'm almost done.

10 MR. SNELL: Okay.

11 Q (By Mr. Kuntz) What do you believe to be  
12 the exposure rates for the TVT Abbrevio?

13 A I would say less than 3 percent.

14 Q And what do you base that on?

15 A That would be based on my own personal  
16 experience with the device, review of the medical  
17 literature, review of the articles that we mentioned  
18 earlier that speak to TVT Abbrevio: de Leval,  
19 Waltregny, Tommaselli. I have them listed in my  
20 Summary of Opinions.

21 MR. SNELL: Go ahead and --

22 Q (By Mr. Kuntz) Have you ever looked at any  
23 of the exposure rates for the TVT-S studies since we  
24 know it uses the laser-cut mesh?

25 A Yeah. I believe the exposure rate for

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1 TVT-S is probably about the same. I think the whole  
2 family of products have about the same erosion,  
3 exposure, perforation, whatever word you want to use,  
4 healing abnormalities.

5 I think the complications with the  
6 exception of bladder perforation are the same across  
7 all the products.

8 Q So do you believe the whole TVT line of  
9 products roughly has the same exposure rate of 3  
10 percent?

11 A Yeah, 3 percent is probably the highest  
12 number I've seen. I've seen it as low as .5 percent.

13 Q So 3 percent is the highest exposure rate  
14 you've seen for the TVT line of products?

15 A Yeah, yes.

16 Q What about erosion rate?

17 A Well, I'm speaking to exposure, and I think  
18 that -- you know, again, that word "erosion" is a  
19 tricky one. I would say if you're meaning urinary  
20 tract erosion, now known as urinary tract  
21 perforation, it would be somewhere around .5 percent  
22 or even less.

23 Q Okay. Give me one second.

24 Do you agree that you're one of the biggest  
25 sling users in Colorado?

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1 MR. SNELL: Objection, form, "sling users."

2 A I realize I have a busy practice in female  
3 pelvic medicine and reconstructive surgery with  
4 respect to my colleagues in this state.

5 Q (By Mr. Kuntz) Do you agree with Ethicon's  
6 assessment, that you're a big advocate of the  
7 Abbrevio?

8 A I don't know how they would -- how they  
9 characterized me, but certainly I stood behind the  
10 product. I did the video. You know, I taught the  
11 procedure. So that would probably qualify me as an  
12 advocate.

13 Q Right. And you've stood behind the TVT  
14 Secur and Prolift in the same way, and they're now  
15 off the market, correct?

16 A I was a preceptor for those products, and I  
17 did videos and studies of papers, abstracts, et  
18 cetera.

19 Q How many depositions have you given in your  
20 career in medical-legal work?

21 A In the last five years?

22 Q No. Ever.

23 A Ever. Somewhere around, I would say, seven  
24 or eight. I'm guessing on the exact number. Less --  
25 certainly less than 15. Probably less than 10.

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1           **Q**     Were any of those in mesh cases?

2           **A**     In recent years, yes.

3           **Q**     Did you testify as an expert witness in  
4     those cases?

5           **A**     No. I've -- this is the first time I've  
6     given deposition as an expert witness.

7           **Q**     Is the Lewis case and this case the only  
8     two cases you've been designated as an expert  
9     witness?

10          **A**     That's correct.

11          **Q**     Okay. Have you ever testified on behalf of  
12     an injured plaintiff in a lawsuit?

13          **A**     The majority --

14                 MR. SNELL: Form. Objection, form, "on  
15     behalf," vague.

16          **A**     I've testified as a treating physician.  
17     I've done that a number of times for my patients.

18          **Q**     (By Mr. Kuntz) On your Summary of Opinions  
19     sheet, did I ask you, did you look at Dr. Grier's  
20     when you were drafting this?

21                 MR. SNELL: Yeah, you already asked him  
22     about this. This is all asked and answered. Go  
23     ahead.

24          **Q**     (By Mr. Kuntz) Is that a "yes" or "no"?

25          **A**     I reviewed Dr. Grier's exhibits, including

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1 his Summary of Opinions.

2 **Q** And you'd agree that some of your summary  
3 of opinions are exactly the same as his summary of  
4 opinions?

5 MR. SNELL: Objection, form. Go ahead.

6 **A** Doug and I had similar practices, and we  
7 think very similarly about this product. So yeah, I  
8 agree that a lot of the statements are similar to  
9 Doug, and they're similar to what 95 percent of  
10 urologists and urogynecologists would say.

11 **Q** (By Mr. Kuntz) And that's based on the  
12 AUGS statement and the papers cited in the AUGS  
13 statement?

14 MR. SNELL: Objection, form.

15 **A** AUGS statements, conversation with  
16 colleagues.

17 **Q** (By Mr. Kuntz) You've never determined an  
18 amount or a percentage of your colleagues that you  
19 talked to as to 95 percent? You don't know that, do  
20 you, Doctor?

21 **A** I wouldn't know the exact number, but I  
22 could easily say that the overwhelming majority of  
23 colleagues that do what I do use mid-urethral mesh  
24 slings.

25 **Q** You've never done any research to see any

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1 institution or doctors who are now not doing slings,  
2 have you?

3 **A** Me, personally, have I done a study?

4 **Q** Yes.

5 **A** No, I haven't surveyed people around the  
6 country, no.

7 **Q** And the only institution you can mention on  
8 record that you know might not be using slings is the  
9 Mayo Clinic, correct?

10 **A** And I don't even know if that's correct.  
11 It may just be hearsay. I've heard people talk about  
12 that, but I've had patients that have gone there that  
13 have had mesh implanted within the last few years.  
14 So I don't even know if the statement is even true.

15 **Q** All right. Who's your dean or your boss at  
16 the University of Colorado?

17 **A** Who's our dean?

18 **Q** Yeah. Who's in charge of your department?

19 **A** Well, the dean of the medical school is  
20 Dick Krugman.

21 **Q** Okay. Who's in charge of conflict of  
22 interest in your department there?

23 **A** Well, ultimately the dean is.

24 **Q** Okay. Do you know the name of any of your  
25 medical students or patients that you've talked to

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1 and discussed the differences between laser-cut mesh  
2 and mechanical-cut mesh in your training sessions?

3 **A** Not medical students or residents, but I  
4 could speak to my fellows. Those are the individuals  
5 that I have the closest relationship with.

6 **Q** Did you ever do a PowerPoint? Do any of  
7 your PowerPoints that you have used with them or  
8 presentations discuss the difference between  
9 laser-cut mesh and mechanical-cut mesh?

10 **A** No.

11 **Q** Okay. But it's your testimony that you  
12 tell them the differences between laser-cut mesh and  
13 mechanical-cut mesh?

14 **A** We have discussions about that, but it's  
15 not a really big point that I emphasize to them one  
16 way or another.

17 And like I mentioned earlier in the  
18 deposition, it was mostly during the transition  
19 years, you know, in and around 2009, 2010, somewhere  
20 around then when the transitioning was happening.

21 It's less relevant these days because all  
22 we've used is laser-cut mesh for the last three to  
23 four years.

24 **Q** Okay. Do you know what -- the percentage  
25 of physicians in the United States that are using

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1 mechanical-cut versus laser-cut mesh?

2       **A**       I don't know the exact number, but I know  
3 people that use the Boston Scientific products and  
4 the Ethicon products use the laser-cut mesh.

5               MR. KUNTZ: Okay. I don't have any more  
6 questions.

7               MR. SNELL: All right. Let's take a break.  
8 I might have some questions, not too many, though.

9               (Recess from 9:02 p.m. to 9:07 p.m.)

10                               EXAMINATION

11 BY MR. SNELL:

12       **Q**       Doctor, you have before you your Summary of  
13 Opinions; is that correct?

14       **A**       That's correct.

15       **Q**       Did we mark that as an exhibit?

16       **A**       It's been marked as part of the Exhibit 8.

17               MR. SNELL: I want to mark it separately as  
18 Flynn D1, just so it gets a separate designation.

19               (The deponent handed Mr. Keith a document.)

20               MR. SNELL: He already has a copy.

21               MR. KEITH: He's giving it to me to mark.

22               MR. SNELL: Oh, okay. Well, here. Give it  
23 to me. I'll mark it.

24               MR. KEITH: So it no longer is contained in  
25 Exhibit 8. It's its own exhibit.

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1 (Exhibit D1 was marked.)

2 Q (By Mr. Snell) Doctor, I've handed you  
3 Exhibit Flynn D1, and identify this document, please,  
4 for the record.

5 A This is Brian J. Flynn's Summary of  
6 Opinions, Coleen Perry versus Ethicon and Johnson &  
7 Johnson. This is a document that I prepared in  
8 preparation for this document.

9 Q And does this document contain a summary of  
10 your opinions?

11 A It does.

12 Q Do you hold these opinions to a reasonable  
13 degree of medical and scientific certainty?

14 A Yes.

15 Q Was your independent medical examination of  
16 Mrs. Perry marked?

17 A Not separately. It was part of 8, similar  
18 to this Summary of Opinions.

19 MR. SNELL: I'm going to mark as Flynn D2 a  
20 copy of the IME.

21 (Exhibit D2 was marked.)

22 Q (By Mr. Snell) And, Doctor, I've marked  
23 your report of your December 19, 2014 IME as Flynn  
24 D2; is that correct?

25 A That's correct.

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1           **Q**     And in that report, do you set forth your  
2     interactions and the medical examination of  
3     Mrs. Perry?

4           **A**     Yes.

5           **Q**     Do you identify your opinions flowing from  
6     your medical examination in that document as well?

7           **A**     Can you repeat the question?

8           **Q**     Sure. Do you set forth your opinions and  
9     conclusions in that document with regard to  
10    Mrs. Perry?

11          **A**     At the end of the document, I have my  
12    assessment and opinions, yes.

13          **Q**     Do you hold those opinions and assessments  
14    to a reasonable degree of medical certainty?

15          **A**     I do.

16          **Q**     Let's start on some topics that were  
17    recently covered by plaintiff's counsel.

18                 Plaintiff's counsel just asked you recently  
19    about your statement that 95 percent of pelvic  
20    surgeons -- or the vast majority of them use mesh  
21    slings TVT mid-urethral slings.

22                 MR. KEITH: Is Jeff on the line?

23                 MR. KUNTZ: Yeah, I'm here.

24          **Q**     (By Mr. Snell) Does Paragraph No. 10 of  
25    your summary identify different surveys of AUGS and

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1 AUA that speak to how commonly mid-urethral slings  
2 are used by your contemporary surgeons?

3 MR. KUNTZ: Objection, compound.

4 A Can you repeat the question?

5 Q (By Mr. Snell) Does Paragraph 10 of your  
6 list of opinions set forth different AUGS and AUA  
7 surveys that speak to whether or not the majority of  
8 surgeons were using TVT, TVT-O, TVT Abbrevio, and  
9 other synthetic mid-urethral slings?

10 MR. KUNTZ: Objection.

11 A Yes.

12 (Mr. Keith left the room.)

13 Q (By Mr. Snell) Your testimony that 3  
14 percent is the higher rate of exposure that you've  
15 seen based on the data, is that based on your review  
16 of various Cochrane reviews and other meta-analyses  
17 that look across large bodies of studies as to  
18 exposure rate?

19 (Mr. Keith entered the room.)

20 A Where that number comes from is, I tried to  
21 give the most conservative estimate of the  
22 complications. Cochrane review is one of them. I  
23 will say -- my own personal experience -- it's much  
24 lower than that.

25 Q (By Mr. Snell) You were asked some

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1 questions about the 1-by-1-centimeter cyst that you  
2 found in Mrs. Perry's vagina at the time of your IME.

3 **A** Yes.

4 **Q** Is the occurrence of cysts something that's  
5 generally known in the medical community?

6 **A** Vaginal cysts?

7 **Q** Yes. That they can appear and then over  
8 time disappear?

9 **A** Certainly.

10 **Q** Is that general medical knowledge to  
11 surgeons who do vaginal inspections?

12 **A** It is.

13 **Q** You were asked some questions about  
14 Mrs. Perry's husband and his claim -- and the claim  
15 that he had an abrasion.

16 First of all, are you aware of Mrs. Perry's  
17 husband claiming any injuries in this case?

18 **A** I don't believe that he's a complainant in  
19 this case. I believe he gave a deposition. He's a  
20 witness, but I don't believe he has his own separate  
21 lawsuit.

22 **Q** You referenced earlier the November 2014  
23 record from Dr. Allen where it noted that Mrs. Perry  
24 apparently told Dr. Allen that her husband had a  
25 penile abrasion.

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1 Do you recall that?

2 **A** Which date?

3 **Q** November 2014 --

4 **A** Yes --

5 **Q** -- the Allen record.

6 **A** -- I recall that.

7 **Q** Was there any mesh exposure found at that  
8 time?

9 **A** Not in November of 2014 on Dr. Allen's exam  
10 or on my December 2014 exam.

11 **Q** So if there was an abrasion to his penis,  
12 as Mrs. Perry reported, do you believe it had  
13 anything to do with the mesh?

14 **A** I don't believe it had anything to do with  
15 the mesh at that point.

16 **Q** You were asked some questions about the  
17 different studies you cite to in your report that  
18 provided dyspareunia rates with posterior  
19 colporrhaphy in excess of 20 percent.

20 Do you recall in general that topic at  
21 Paragraph 34?

22 **A** Yes.

23 **Q** One of those articles is the Komesu article  
24 that you say had a 57 percent postoperative  
25 dyspareunia rate.

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1 Do you see that?

2 **A** I do.

3 **Q** Do you remember you were asked about any --  
4 whether some of these studies had levatorplasties  
5 performed concomitantly in them?

6 **A** I was asked about whether or not  
7 levatorplasty would make it more likely or less  
8 likely to have dyspareunia.

9 **Q** I have here the Exhibit 25, your files that  
10 you produced. The Komesu article, Posterior Repair  
11 and Sexual Function, is that the study you  
12 referenced?

13 **A** I referenced five studies, but that's one  
14 of them.

15 **Q** And for that one, if we look at the Result  
16 section on the first page, tell me -- let's see. It  
17 talks about the PR group. Is that the posterior  
18 repair group?

19 **A** Yeah. No PR. No posterior repair -- PR  
20 group, posterior repair.

21 **Q** And does this state, "None of the patients  
22 had levatorplasty performed"?

23 **A** That's a correct statement.

24 **Q** And so in this study where there was a 57  
25 percent postoperative dyspareunia rate, none of those

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1 patients had levatorplasty; is that correct?

2 MR. KUNTZ: Objection.

3 A That's correct.

4 Q (By Mr. Snell) And you also cite to Karram  
5 and Maher 2013, Tables 1 and 2, which you say shows  
6 multiple studies documenting dyspareunia rates in  
7 excess of 20 percent.

8 A Yes. Table 1 of that study, there is -- it  
9 looks like nine studies listed in the incidents of  
10 dyspareunia. It ranges from a low of 8 percent to as  
11 high as 45 percent.

12 Q And then Table 2 has posterior vaginal  
13 repair rates of dyspareunia. That's what you also  
14 referenced at Table 2?

15 A Yeah, and that table pertains to  
16 site-specific repair.

17 Q And that's 19 percent, 46 percent, and  
18 various different rates of dyspareunia, correct?

19 A It looks like there's a wide range, like  
20 Table 1, somewhere between 7 and 45 percent.

21 Q And in that study at Page 1837, when  
22 they're talking about site-specific defect repairs  
23 and they're discussing the technique, they say,  
24 "Traditional levatorplasty is avoided"; is that  
25 correct?

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1 MR. KUNTZ: Objection.

2 A I don't believe levatorplasty is considered  
3 part of site-specific defect repair.

4 Q (By Mr. Snell) And in that study under  
5 Site-Specific Defect Repair, it states, "Traditional  
6 levatorplasty is avoided"; is that correct?

7 A That's correct.

8 Q And in that table -- it points to Table 2.  
9 So even in the posterior colporrhaphies where they  
10 avoid levatorplasty, is it your opinion that they can  
11 still have significant dyspareunia rates?

12 A Any posterior repair can give you  
13 dyspareunia regardless of the technique.

14 Q You were asked questions about the hCG  
15 diet. Does Paragraph 33 of your opinions state what  
16 you found significant with regard to her healing  
17 complication?

18 A I think Paragraph 33, you know, speaks to  
19 her use of the hCG diet as recommended by Dr. Singh,  
20 side effects that she incurred such as light-  
21 headedness, headaches, and blurred vision.

22 And I feel that that may have been due to  
23 her catabolic state, and that catabolic state would  
24 impair wound healing. That was one of the factors  
25 that I identified in contributing to her wound

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1 dehiscence.

2           **Q**     Do you have an understanding as to the  
3 number of calories that that diet would restrict  
4 Mrs. Perry to?

5           MR. KUNTZ: Objection, speculation.

6           **A**     I don't know the exact caloric restriction.  
7 I would say probably less than -- less than 500. You  
8 know, it's coupled with off-label pregnancy hormone  
9 injections. So it's hard to say, but I mean, it's  
10 somewhere around 500, but it did lead to a 19-pound  
11 weight loss.

12          **Q**     (By Mr. Snell) And would a 500-calorie  
13 diet lead to a catabolic state?

14          MR. KUNTZ: Objection.

15          **A**     In someone of her size and weight, yes.

16          **Q**     (By Mr. Snell) And you believe that that  
17 was a contributing factor to her mesh exposure, the  
18 wound healing problem that she developed?

19          **A**     Yeah, I believe that is one of the factors  
20 that I list, along with smoking and some of the other  
21 factors that we've identified.

22                 So she had, you know, multiple risk  
23 factors: weight loss, smoking, anterior vaginal wall  
24 incision, her obesity.

25          **Q**     Let's go back.

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1 Earlier in the deposition you were asked  
2 about different ways a doctor could tell if a mesh  
3 was laser-cut. Let me ask you: By looking -- just  
4 looking at the TVT Abbrevio sling, itself, can you  
5 tell it's laser-cut?

6 **A** Yes, I can.

7 **Q** Is that obvious to you as a physician?

8 **A** If you're familiar with the  
9 mechanically-cut and laser-cut, yes, I believe you  
10 can see the differences.

11 **Q** And do you believe there's any difference  
12 -- any clinically significant difference between the  
13 mechanical-cut and laser-cut meshes?

14 **MR. KUNTZ:** Asked and answered. I mean, we  
15 have been through this about five times. You stopped  
16 me from asking. I don't know why you need to ask it  
17 again, but go ahead.

18 **A** I don't believe there's any difference  
19 based on my review of the literature, based on my own  
20 personal experience.

21 If you look at the data from '98 to in and  
22 around 2006 to the data from 2006 to current, the  
23 wound complications, exposure rates, perforations are  
24 essentially the same, as well as the efficacy of the  
25 two products are the same.

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1           So there was a lot of discussion, a lot of  
2   strong personal opinions, but that's all it amounted  
3   to be.

4           **Q**     (By Mr. Snell) You were asked earlier  
5   about whether there was any study or paper you can  
6   point to that showed dyspareunia or longer-term pain  
7   as a risk factor with Burch procedure.

8           Do you have a paper by Demirci as one of  
9   the papers you reviewed?

10          **A**     I do, and it was part of --

11          **Q**     What's that part of?

12          **A**     -- Exhibit 8.

13          **Q**     Did that study report on whether any  
14   patients who got the Burch had dyspareunia at some  
15   follow-up of greater than one year?

16          **A**     Looking at the abstract, the dyspareunia  
17   occurred in six patients out of the 220 patients.

18          **Q**     Was there any groin -- or pain -- any other  
19   pain in that study?

20                 MR. KUNTZ: Objection, leading.

21          **A**     There was --

22          **Q**     (By Mr. Snell) Hold on. Withdrawn.

23                 Was there any other type of pain documented  
24   in that Burch study?

25                 MR. KUNTZ: Objection.

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1           **A**     Yes, there was.

2           **Q**     (By Mr. Snell) And what was it?

3           **A**     Groin pain and suprapubic pain.

4           **Q**     And what was the follow up in that study  
5 for the two different parts?

6           **A**     4.5 years versus -- 1.5 year for Group 1.  
7 4.5 years for Group 2.

8           **Q**     And in Paragraph 13 of your report, you  
9 list pain, pelvic pain, groin pain, and dyspareunia  
10 as risks of incontinence and prolapse surgery; is  
11 that correct?

12          **A**     That's correct.

13          **Q**     And you state that those are basic  
14 elemental surgical risks?

15          **A**     That's correct.

16          **Q**     Are those risks that surgeons would even  
17 know of or should know of based on their medical  
18 school, residencies, and surgical training?

19                 MR. KUNTZ: Objection.

20          **A**     I think there's a variety of ways  
21 physicians obtain that information, but certainly  
22 medical school, residency, fellowship, their own  
23 personal practice is fundamental in formulating an  
24 understanding of the risks and benefits of pelvic  
25 surgery.

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1           **Q**       (By Mr. Snell) In Paragraph 14, you note  
2       that, "Complications are known to occur and range  
3       from not troubling to mild, moderate, or severe; and  
4       they can be temporary or chronic, which is basic  
5       surgical knowledge that all pelvic floor surgeons  
6       would know or would be expected to know"; is that  
7       correct?

8                   MR. KUNTZ: Objection.

9           **Q**       (By Mr. Snell) Is that correct?

10          **A**       I would say that all surgeons, not just  
11       pelvic surgeons -- all surgeons should be aware of  
12       complications. The very first thing we mention to  
13       patients when we're doing informed consents, the  
14       risks: bleeding, infection, pain. Those three  
15       things can happen virtually with any surgeon.

16          **Q**       And is that basic elemental surgical  
17       knowledge?

18                   MR. KUNTZ: Objection.

19          **A**       That's fundamental knowledge.

20          **Q**       (By Mr. Snell) You were asked questions  
21       about the gold standard, and I believe you testified  
22       you believe that TVT, TVT Abbrevio, TVT-O are  
23       considered, in your opinion, the gold standard or  
24       within the gold standard.

25          **A**       Within the gold standard, yes.

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1           **Q**     And of the gold standard slings, are there  
2     any who have more data and study than the TVT mesh  
3     family?

4           **A**     It's the most widely studied incontinence  
5     procedure.

6                   MR. KUNTZ:  Objection.  Are you talking  
7     about TVT or TVT Abbrevio?

8                   MR. SNELL:  You're not questioning here.  I  
9     am.  I said the TVT family mesh.

10                  MR. KUNTZ:  You told me I had to state the  
11     reason for my objection.

12                  MR. SNELL:  Okay.  Well, then state it  
13     properly.  Don't ask him a question.

14                  MR. KUNTZ:  All right.  Objection.

15                  MR. SNELL:  I said TVT family of mesh.

16           **Q**     (By Mr. Snell)  Doctor, do you know if the  
17     same mesh is used in --

18                  MR. KUNTZ:  And I said that --

19           **Q**     (By Mr. Snell)  -- TVT --

20                           (All speaking simultaneously, and reporter  
21     requested clarification.)

22                  MR. KUNTZ:  -- three different products.  
23     Compound -- or four different products.  So which one  
24     are you talking about for the most studied?

25           **Q**     (By Mr. Snell)  Doctor, do you know if the

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1 same mesh is used in TVT Retropubic, TVT-O, and the  
2 TVT Abbrevio?

3 MR. KUNTZ: Objection. It misstates the  
4 evidence in the case.

5 Q (By Mr. Snell) The same polypropylene  
6 mesh?

7 A Yes.

8 Q All right. And for that TVT family of  
9 meshes that's the same mesh, is there --

10 MR. KUNTZ: Objection.

11 Q (By Mr. Snell) -- any other mesh in the  
12 world that's been studied as much as that mesh?

13 MR. KUNTZ: Objection, compound. Are you  
14 talking about TVT Abbrevio, TVT-O laser-cut, TVT  
15 Retropubic laser-cut?

16 MR. SNELL: I'm not worried about that.

17 MR. KUNTZ: I know you're not --

18 MR. SNELL: You're asking questions --

19 MR. KUNTZ: -- worried about it --

20 (All speaking simultaneously, and  
21 reporter requested clarification.)

22 MR. SNELL: I'm going to object --

23 MR. KUNTZ: -- the question the right way.

24 MR. SNELL: Pose a form objection properly.  
25 Quit asking him questions and asking questions that

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1 mean nothing --

2 MR. KUNTZ: It's okay to --

3 MR. SNELL: Pose a proper objection.

4 That's it.

5 MR. KUNTZ: I will. Objection. It's  
6 compound because we don't know whether you're talking  
7 about Abbrevio laser-cut, TVT-O laser-cut, TVT-O  
8 mechanical-cut.

9 You told me under California rules I have  
10 to give you the reason and the basis to correct your  
11 question. So it's compound because you're talking  
12 about six different products.

13 MR. SNELL: All right.

14 MR. KUNTZ: So if you want to ask him  
15 individually --

16 MR. SNELL: No, no, no. That's your basis.  
17 Don't tell me how to ask my questions. I'm asking  
18 about the TVT family of mesh that this witness has  
19 testified is the same, and in his opinion there's no  
20 clinical difference for mechanical-cut and laser-cut.

21 So that's what I'm asking about.

22 MR. KUNTZ: Objection. We don't know which  
23 product you're talking about.

24 MR. SNELL: Okay. I know what I'm talking  
25 about, and I know what the witness is testifying to.

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1 MR. KUNTZ: I beg to differ, but that's all  
2 right.

3 Q (By Mr. Snell) This mechanical-cut versus  
4 laser-cut, that's not something you think is even  
5 clinically relevant; is that correct or not?

6 A Not at this point.

7 Q And so for the TVT family of meshes,  
8 whether they are laser-cut or mechanical-cut, is  
9 there any other family of meshes that has been  
10 studied as much as the TVT family of meshes?

11 A No.

12 Q And you have documents in your file in  
13 probably one of these exhibits that show over 100  
14 randomized controlled trials with the TVT family of  
15 meshes?

16 A That's correct.

17 MR. KUNTZ: Objection.

18 Q (By Mr. Snell) In Paragraph 16, you  
19 identify several long-term studies, you say, support  
20 the safety and efficacy up to 17 years. "Efficacy in  
21 these studies is generally consistently in the 80 to  
22 90 percent range with low complications and very few  
23 late-term complications."

24 Did I read that correctly?

25 A That's correct.

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1           **Q**     Okay.

2                   MR. KUNTZ:  Objection.

3           **Q**     (By Mr. Snell)  Are there any other meshes  
4     besides the TVT family of mesh that has longer-term  
5     data than that group of meshes?

6                   MR. KUNTZ:  Objection.

7           **A**     For stress urinary incontinence?

8           **Q**     (By Mr. Snell)  Exactly.

9           **A**     There's no other product that has been  
10    studied as extensively or for as long a duration as  
11    the TVT SUI products.

12          **Q**     In Paragraph 21 -- you were asked some  
13    questions about degradation, correct?

14          **A**     Correct.

15          **Q**     In Paragraph 21, you state that those  
16    long-term clinical studies showing lasting success  
17    are inconsistent with the degradation theory; is that  
18    correct?

19          **A**     That's correct.

20          **Q**     And what do you mean by that?

21          **A**     Well, if you look at the -- more than 100  
22    RCTs and more than 1,000 articles in the  
23    peer-reviewed literature looking at clinical results  
24    of TVT and if you ask me about my own personal  
25    experience, there is no evidence of degradation in

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1 the clinical literature.

2 The degradation theory that's been proposed  
3 is related to mesh explants, and specifically the  
4 conversation comes from a select number of articles  
5 that have only been published in the last five years,  
6 the Clave article that we mentioned earlier, Patel.  
7 There's a Costello case report.

8 Q You were asked some questions about -- in  
9 the original TVT Abbrevio study about whether there  
10 was some mechanically-cut, and I believe you  
11 testified you saw in Dr. Rosenzweig's deposition a  
12 reference to an e-mail or document from Pete Hinoul  
13 that said maybe half were mechanical-cut and half  
14 were laser-cut.

15 Do you recall that?

16 A I recall that.

17 MR. KUNTZ: Objection.

18 Q (By Mr. Snell) And do you recall whether  
19 there were any exposures in that one-year data?

20 A Not in the Hinoul study.

21 MR. KUNTZ: Ooh, wow.

22 Q (By Mr. Snell) Do we have the de Leval  
23 study here?

24 A The one-year or the three-year?

25 Q The one-year that Dr. Rosenzweig was

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1     testifying about.

2           **A**     I'm going to go into the folder, the  
3     labeled Exhibit 8.

4           **Q**     I think you had that in one of the other  
5     folders, the big SUI folder. Did you put it over  
6     there (indicating)? It was in the big one that had  
7     all the tabs, I thought.

8           MR. KEITH: Exhibit 16?

9           MR. SNELL: Yeah, I think that might have  
10    been it. Let's see if this is the one.

11          **Q**     (By Mr. Snell) Do you see in the de Leval  
12    study where it states, "One patient in the original  
13    TVT-O procedure developed a suburethral vaginal  
14    exposure of the mesh."

15                 Do you see that?

16          **A**     I do.

17          **Q**     And then, "No other mesh exposure  
18    complications were observed during follow-up." Do  
19    you see that?

20          **A**     Yep.

21          **Q**     And if Dr. Rosenzweig opined that he  
22    believed that this study showed that there was more  
23    mesh exposure with a laser-cut mesh, would that study  
24    support that opinion?

25          **A**     No, it would not.

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1           **Q**     Earlier you pointed out in the Method  
2     section of this paper that some of the -- with the  
3     first modification, tape shortening was carried out  
4     directly in the operating theater.

5           **A**     Yes.

6           **Q**     How would that be done?

7           **A**     Well, that can be carried out a variety of  
8     ways. You can feed a suture through the ends. You  
9     can mechanically cut the mesh at the edges with your  
10    scissors.

11                   There's obviously ways of shortening  
12    meshes. We alter meshes all the time when we implant  
13    them to try to make them fit. It's not one size fits  
14    all. Even on full-length slings we have to cut the  
15    mesh where it exits the skin when we're deploying the  
16    mesh. So I think that's what de Leval is getting at.

17           **Q**     You were asked some questions about foreign  
18    body response. Do you recall, in general, that  
19    topic?

20           **A**     I do.

21           **Q**     Is the foreign body response taught to  
22    surgeons during their medical school and residencies  
23    and training?

24           **A**     Yes.

25           **Q**     Is that common, elemental surgical

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1 knowledge?

2           **A**     Yes. I mean, you have classes and  
3 pathology and histology, pathophysiology where you're  
4 going to review those mechanisms, immunology.

5           **Q**     And when you testified earlier you believe  
6 the IFU is adequate and there are certain things that  
7 are already known or should be known by pelvic  
8 surgeons, are you giving that opinion from the  
9 perspective of a pelvic floor surgeon?

10          **A**     Yes.

11          **Q**     As the -- an intended user of the product,  
12 the TVT Abbrevo?

13          **A**     That's correct.

14          **Q**     The one who would read the IFU and  
15 understand the IFU; is that correct or not?

16          **A**     I think I mentioned earlier I think the  
17 physician has a responsibility to educate themselves  
18 on the products they're using. The IFU is one of the  
19 tools that's used for that.

20          **Q**     So earlier when you testified to Mr. Kuntz  
21 that although a word like "dyspareunia" -- that word  
22 wasn't in the IFU, there were adverse reactions that  
23 to you, as a pelvic floor surgeon -- said to you,  
24 these could lead to dyspareunia, is that -- were you  
25 testifying from the perspective of a pelvic floor

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1 surgeon?

2 MR. KUNTZ: Objection.

3 A Yes.

4 Q (By Mr. Snell) You were asked a question  
5 about whether you offered to allow Mrs. Perry to  
6 utilize the restroom before your IME.

7 Do you recall being questioned about that?

8 A I do.

9 Q Is that something you would offer your  
10 patients, if they would like to use the restroom?

11 A I want patients to be comfortable when I  
12 examine them, so yeah, that's a standard part of my  
13 practice with patients. Entering the clinic often  
14 we'll get a urine sample, and they'll empty their  
15 bladder during those time periods.

16 Q In Paragraph 18, you talk about the Boston  
17 Science Obtryx SUI device.

18 A Yes.

19 Q And that's -- is that your understanding,  
20 that that's the device that Dr. Luu testified he  
21 uses?

22 A Currently.

23 Q What's the pore size of that device?

24 A The pore size, I believe, is very similar  
25 to the Ethicon device.

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1           **Q**     Paragraph 18.

2           **A**     So the pore size is 1,182 microns or  
3 micrometers. The weight is 100 grams per meter  
4 squared.

5           **Q**     And the TVT Abbrevio, is the pore size --  
6 how does the pore size compare to the Boston  
7 Scientific Obtryx?

8           **A**     Slightly larger at 1,379 micrometers. The  
9 weight is identical at 100 grams per meter squared.

10          **Q**     You were asked a question -- a couple of --  
11 actually, quite a few questions about the edges of  
12 the mechanical- and the laser-cut.

13                 For which of those two meshes is the edge  
14 of the mesh smoother?

15          **A**     Just to be clear, for the record, the  
16 laser-cut mesh is smoother, meaning it has nontanged  
17 edges -- those are often how the edges are described.  
18 Smoother, nontanged -- where the mechanically-cut  
19 mesh tends to have some fraying at the edges.

20          **Q**     The -- you were asked questions about AUGS,  
21 AUA, and various statements. Do you believe that the  
22 TVT Abbrevio is a mid-urethral polypropylene sling  
23 which is encompassed within those position  
24 statements?

25          **A**     It's a --

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1 MR. KUNTZ: Objection.

2 A It's a mid-urethral transobturator  
3 polypropylene sling.

4 Q (By Mr. Snell) And is it standard of care?

5 A I believe it's a commonly used product.  
6 It's -- the whole family of products are part of the  
7 standard of care, the most common procedures used.

8 Q And do you believe that the TVT Abbrevio is  
9 encompassed within those position statements and  
10 guidelines?

11 MR. KUNTZ: Objection.

12 A I do.

13 Q (By Mr. Snell) And . . .

14 (Pause.)

15 Q You were asked to draw or illustrate --  
16 Exhibit 29 -- some different parts of the vagina and  
17 where the sling was. Do you recall that?

18 A Yes.

19 Q Is it your understanding or opinion that  
20 the incision made at the anterior wall was a long,  
21 single incision?

22 A In my understanding from review of  
23 Dr. Luu's operative report, is that there was one  
24 single incision anteriorly that allowed placement of  
25 the TVT Abbrevio, as well as the anterior

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1     colporrhaphy.

2           **Q**     And the scoring that was noted to the  
3     anterior wall -- first of all, let me back up.

4                   Does an anterior colporrhaphy -- is part of  
5     that procedure designed to cause scarring?

6           **A**     I think any surgery can cause scarring.  
7     Some have that as a specific intent. So the  
8     scarification can lead to reinforcement and  
9     fiberglass growth and infiltration and actually cause  
10    strengthening of that area.

11          **Q**     And do you believe that the anterior  
12    colporrhaphy caused scarring to her anterior vaginal  
13    wall?

14          **A**     Yes.

15          **Q**     And the posterior colporrhaphy and the  
16    perineoplasty, did they cause scarring to her vagina  
17    as well?

18          **A**     To the posterior vagina and to the perineal  
19    body, yes.

20          **Q**     In Dr. Allen's record of January 2012, it  
21    states that, "Mrs. Perry stated her problem was that  
22    her vagina felt too tight at the opening, and this is  
23    what makes it painful for her to have sex."

24                   Did I read that correctly?

25          **A**     Yes. That's a statement directly from

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1 Dr. Allen's note on November 11, 2012.

2 Q And is that statement consistent or  
3 inconsistent with your opinion that her posterior  
4 colporrhaphy and the perineoplasty were the cause of  
5 her pain?

6 A That would be consistent with that opinion.

7 Q And a little further down Mrs. Perry  
8 reports that her husband got an abrasion. Do you see  
9 that?

10 A I see that.

11 Q And Dr. Allen advised the patient of  
12 various different options at this time?

13 A Yes.

14 Q I believe you were asked questions about  
15 inflammation or chronic inflammation. Let me ask  
16 you: Do you have an opinion as to whether Mrs. Perry  
17 had chronic inflammation in her vaginal tissues  
18 before the TVT Abbrevio was put in?

19 A Yes, I have an opinion in regards to that.

20 Q What is that?

21 A That she's had chronic inflammation in that  
22 area that was based on previous evidence.

23 Q And do you see the pathology report as to  
24 whether it stated she had chronic inflammation in her  
25 vaginal tissues?

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1           **A**       Yeah. That's based on my review of the  
2 pathology report. It's based on my review of the  
3 medical records, her long-term history that she  
4 reported pelvic pain, dyspareunia, other procedures  
5 that she's had done, including what sounds like an  
6 endometrial ablation using cryo.

7                   So this is a patient that's had a long-term  
8 history of pelvic floor disorders, including pelvic  
9 pain and urinary incontinence.

10          **Q**       I think you were asked about some of the  
11 longer-term data with the TV -- with the  
12 transobturator TVT products. Do you recall that?

13          **A**       Yes.

14          **Q**       And what's this exhibit plaintiff's counsel  
15 marked? So within Exhibit 8, do you have various  
16 long-term transobturator TVT-O studies?

17          **A**       I do.

18          **Q**       And do you believe the TVT-O and the TVT  
19 Retropubic studies are applicable to the TVT Abbrevio  
20 studies?

21                   MR. KUNTZ: Objection.

22          **A**       Can you be more specific about the word  
23 "applicable"?

24          **Q**       (By Mr. Snell) Do you believe they are  
25 relevant considering that you testified that they use

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1 the same mesh?

2 **A** Yes --

3 MR. KUNTZ: Object.

4 **A** -- I believe that's valuable information.

5 **Q** (By Mr. Snell) In the AUA statement, it  
6 says, "Multiple case series and randomized control  
7 trials attest to the efficacy of synthetic  
8 polypropylene mesh slings at 5 to 10 years."

9 Did I read that correctly?

10 **A** You did.

11 **Q** Is that consistent or inconsistent with  
12 your investigation of the longer-term data on the TVT  
13 and the TVT-O Ethicon products?

14 **A** I believe that the Ethicon products can be  
15 included in that statement. They meet the criteria  
16 as defined by AUA and by AUGS and by SUFU.

17 **Q** I just want to make sure we have one thing  
18 clear, too.

19 In the IME report -- you were asked about  
20 the pharmacologic therapy and vaginal massage and  
21 those other potential modalities.

22 Do you recall that?

23 **A** I do.

24 **Q** And you say, "She may consider." Is it  
25 your opinion that these are things -- strike that.

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1           It seemed to me that it was suggested that  
2   these were recommendations that you were making that  
3   she actually needed. Is that inconsistent -- or  
4   strike that.

5           When you say "She may consider  
6   pharmacologic therapy," what did you mean by "may  
7   consider"?

8 MR. KUNTZ: Objection.

9           **A**       In my opinions, I'm just trying to offer  
10       opinions for options that the patient may consider  
11       going forward with her practitioners, Dr. Allen or  
12       other future practitioners.

13           Q        (By Mr. Snell) You weren't stating that  
14 she needed to have those procedures?

15 MR. KUNTZ: Objection, leading, asked and  
16 answered.

17 MR. SNELL: I just want to make sure we  
18 have it correct.

19           **A**     I'm not saying what she needs or what she  
20     doesn't need.

21 MR. SNELL: Okay. That was the last one I  
22 had. Thank you.

23 EXAMINATION

24 BY MR. KUNTZ:

25       **Q**     Doctor, I have a few questions for you.

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1           If you go back to your Summary of Opinions,  
2   Item No. 16, where you list, I believe, 16 different  
3   studies that support long-term data supporting the  
4   TVT Abbrevio.

5           **A**     Yes.

6           **Q**     Do you see that?

7           **A**     I do.

8           **Q**     You would agree not one of those studies, A  
9   through P, deals with the TVT Abbrevio, correct?

10           MR. SNELL: Objection, form, "deals with,"  
11   vague.

12           MR. KUNTZ: Okay. I'll restate it.

13           **Q**     (By Mr. Kuntz) Well, tell me this. Go  
14   through these studies, A through P, and tell me which  
15   one relates to the Abbrevio.

16           MR. SNELL: Objection, form.

17           **A**     I believe all of them do.

18           **Q**     (By Mr. Kuntz) And what's your basis for  
19   that opinion?

20           **A**     My basis is that the TVT mesh across the  
21   family of products is basically identical, whether  
22   it's laser-cut or mechanically-cut.

23           So I think you can infer that the  
24   experience with the other products can be applicable  
25   to descriptions of the TVT Abbrevio or future products

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1 that Ethicon may develop. It's the same mesh.

2 Q For example, Nilsson's 11-year follow-up  
3 study and 17-year follow-up study you believe is  
4 applicable to the TVT Abbrevio because it's the same  
5 mesh clinically?

6 A Correct.

7 Q Okay. And scientifically?

8 A Correct.

9 Q And so any study testing any type of TVT  
10 Prolene mesh, whether it's mechanical-cut or  
11 laser-cut mesh, can apply to any of the TVT line of  
12 products; that's your testimony?

13 MR. SNELL: Objection. It misstates.

14 A I think there's going to be an application.  
15 There's going to be relevance. Yes.

16 Q (By Mr. Kuntz) Okay. Because laser-cut  
17 mesh and mechanical-cut mesh are clinically the same?

18 A That's my testimony.

19 MR. KUNTZ: Okay. No further questions.

20 EXAMINATION

21 BY MR. SNELL:

22 Q Doctor, you have seen where TVT-O and TVT  
23 Abbrevio have been studied in the same study, and I  
24 think you list some of them in Paragraph 26, the  
25 Waltregny and de Leval. We already talked about the

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1 Tommaselli paper and the Shah study.

2 Do you recall those?

3 **A** Yes.

4 **Q** And was it your opinion that the efficacy  
5 was essentially the same for the TVT Abbrevos and the  
6 TVT-O?

7 **A** Yes.

8 **Q** And is that consistent or support for your  
9 opinion that there is no real clinical significant  
10 difference between mechanical- or laser-cut?

11 **A** Yeah. I think there's no difference  
12 between laser-cut and mechanically-cut, and I don't  
13 think there's a difference between full-length TVT  
14 Obturator and the 12-centimeter TVT Abbrevo.

15 In my experience, the products behave  
16 identically.

17 **Q** Okay.

18 MR. KUNTZ: Is that it?

19 **Q** (By Mr. Snell) And then TVT Secur, you  
20 were asked about that product. That's actually a  
21 mini sling, correct?

22 **A** TVT is an 8-centimeter sling, so I would  
23 classify it as a mini sling.

24 **Q** And that's also a single incision, correct?

25 **A** That's single incision.

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1           **Q**     It's put in differently than the TVT-O and  
2     TVT Abbrevio?

3           **A**     TVT-O and TVT Abbrevio are multi-incision  
4     slings. TVT Secur was a single-incision sling.

5           MR. SNELL: Okay. That's all I have.

6                                 EXAMINATION

7     BY MR. KUNTZ:

8           **Q**     And, Doctor, when you -- this is -- when  
9     you were out talking to physicians, talking in  
10    cadaver labs and training your students based on all  
11    the knowledge you have from Ethicon, you tell them  
12    that the laser-cut mesh and the mechanically-cut mesh  
13    is the same and there's no clinical difference,  
14    correct?

15          **A**     I do at this point, yes.

16          MR. KUNTZ: Okay. Thank you. No further  
17    questions.

18          MR. SNELL: Thanks.

19          MR. KUNTZ: Hopefully I will see you out in  
20    California.

21          MR. SNELL: Okay. Thank you.

22                         (Discussion off the record.)

23          MR. SNELL: I'm going to make a statement  
24    for the record. I want everything marked that he  
25    brought because everything he is relying on is in his

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1 materials list brought here hard copy electronically.

2 So I just want it stated and everything  
3 marked. So I thought you were going through and  
4 marking everything. If there's things you didn't  
5 mark, I need to know that because I'm going to mark  
6 them.

7 MR. KEITH: As counsel knows, it's a grand  
8 amount of material, including much loose-leaf  
9 material, but to the best of my knowledge and ability  
10 as a lawyer that's been practicing for 20 years, I  
11 believe that I marked everything that the doctor  
12 brought.

13 Now, some of those things are loose and  
14 they are contained within exhibits such as Exhibit  
15 No. 8. That's probably the most clear example of the  
16 loose, but yes.

17 MR. SNELL: I just want to make sure  
18 everything he brought we marked.

19 MR. KEITH: Well, I would suggest that you  
20 go through and make sure it's all -- 1 through 29  
21 because I trust you to do that.

22 MR. KUNTZ: How are we going to get this  
23 stuff copied?

24 MR. KEITH: They're going to come pick it  
25 up in the morning here, the court reporter.

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1 MR. KUNTZ: Okay. And they know we need a  
2 quick turnaround?

3 MR. KEITH: Can we go off the record?

4 MR. KUNTZ: Yeah.

5 MR. SNELL: Just one second just to make  
6 sure.

7 MR. KEITH: Let's go off the record.

8 MR. SNELL: Hold on. I have one last  
9 question for Dr. Flynn.

10 EXAMINATION

11 BY MR. SNELL:

12 Q You brought all the materials here, your  
13 reliance list, the CDs, documents, thumb drives, hard  
14 copy materials that you're relying on?

15 A Correct.

16 MR. SNELL: Okay. So we'll try to make  
17 sure -- here counsel -- there's a lot of materials,  
18 and we will try to make sure that everything gets  
19 marked, and at this point we're up to 29 or 30  
20 exhibits, right? So I think that's everything.

21 MR. KUNTZ: We need copies of thumb drives  
22 and copies of everything, but somebody is coming to  
23 pick those up to copy them tomorrow?

24 MR. KEITH: That's correct. Can we go off  
25 the record?

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1 MR. SNELL: Sure.

2 (The deposition concluded at 9:59 p.m.,  
3 January 7, 2015.)  
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1 STATE OF COLORADO)

2 ) ss. REPORTER'S CERTIFICATE

3 COUNTY OF DENVER )

4 I, Dianna L. Buckstein, do hereby certify  
5 that I am a Professional Shorthand Reporter and  
6 Notary Public within the State of Colorado; that  
7 previous to the commencement of the examination, the  
8 deponent was duly sworn to testify to the truth.

9 I further certify that this deposition was  
10 taken in shorthand by me at the time and place herein  
11 set forth, that it was thereafter reduced to  
12 typewritten form, and that the foregoing constitutes  
13 a true and correct transcript.

14 I further certify that I am not related to,  
15 employed by, nor of counsel for any of the parties or  
16 attorneys herein, nor otherwise interested in the  
17 result of the within action.

18 In witness whereof, I have affixed my  
19 signature this 12th day of January, 2015.

20

My commission expires November 25, 2017.

21

22

23

\_\_\_\_\_  
Dianna L. Buckstein

24

216 - 16th Street, Suite 600

Denver, Colorado 80202

25

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1 INSTRUCTIONS TO WITNESS

2

3 Please read your deposition  
4 over carefully and make any necessary  
5 corrections. You should state the reason  
6 in the appropriate space on the errata  
7 sheet for any corrections that are made.

8 After doing so, please sign  
9 the errata sheet and date it.

10 You are signing same subject  
11 to the changes you have noted on the  
12 errata sheet, which will be attached to  
13 your deposition.

14 It is imperative that you  
15 return the original errata sheet to the  
16 deposing attorney within thirty (30) days  
17 of receipt of the deposition transcript  
18 by you. If you fail to do so, the  
19 deposition transcript may be deemed to be  
20 accurate and may be used in court.

21

22

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25

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E R R A T A

2 - - - - -

3

4 PAGE LINE CHANGE

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24 REASON: \_\_\_\_\_

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2

ACKNOWLEDGMENT OF DEPONENT

3

4

I, \_\_\_\_\_, do

5

hereby certify that I have read the

6

foregoing pages, and that the same is

7

a correct transcription of the answers

8

given by me to the questions therein

9

propounded, except for the corrections or

10

changes in form or substance, if any,

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noted in the attached Errata Sheet.

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\_\_\_\_\_  
BRIAN FLYNN, M.D.

\_\_\_\_\_  
DATE

16

17

18

Subscribed and sworn

to before me this

19

\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_.

20

My commission expires: \_\_\_\_\_

21

22

\_\_\_\_\_  
Notary Public

23

24

25

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1	LAWYER'S NOTES		
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